

The Investigation of the Effect of Hyperglycemic Changes on Psychophysical Measurements of Visual Function in Pseudophakic People Living with Diabetes Mellitus

Lindokuhle Majola¹
Alvin J Munsamy²

¹Department of Health, Port Shepstone, South Africa; ²Discipline of Optometry, School of Health Science, University of KwaZulu-Natal, Durban, South Africa

Purpose: The purpose of this study was to show the effect of increasing blood glucose level (BGL) on psychophysical visual function represented by visual acuity and contrast sensitivity in pseudophakic people living with diabetes (PDM).

Study Design: This was quasi-experimental, quantitative study using a pretest–posttest approach.

Methods: The study was conducted at Gamalakhe community health centre located in Gamalakhe township and included a sample of 50 pseudophakic people living without diabetes mellitus (PWDM) and 50 pseudophakic PDM. BGL as well as psychophysical measurements of visual function were measured preprandial and postprandial. Visual acuity (VA) was measured at distance (4 m) and near (40 cm) using logMAR VA charts, and contrast sensitivity (CS) was measured at 50 cm using a Mars chart. The data collected were captured and subsequently analyzed using SPSS version 25.

Results: Glycemic changes measured preprandial and postprandial observed a mean increase of 2.06 ± 1.35 mmol/L ($p=0.350$) and 1.08 ± 0.47 mmol/L ($p=0.291$) in pseudophakia PDM and pseudophakic PWDM, respectively. CS showed a mean increase of 0.01 ± 0.10 ($p=0.23$) and 0.002 ± 0.02 ($p=0.19$) log units in PDM and PWDM, respectively; however, the independent *t*-test showed this was insignificant between PDM and PWDM ($p=0.27$). A insignificant mean increase of 0.01 ± 0.04 log units ($p=0.25$) and 0.001 ± 0.01 ($p=0.32$) in distance VA of pseudophakic PDM and PWDM was found, respectively. A mean increase of 0.001 ± 0.01 log units ($p=0.32$) and 0.01 ± 0.03 ($p=0.06$) near logMAR VA of pseudophakic PDM and PWDM was found, respectively.

Conclusion: Acute hyperglycemic changes do not result in overall significant changes in visual acuity and contrast sensitivity in pseudophakic PDM and PWDM for an increase in glycemia of 2 mmol/L. We recommend studies investigate if changes occur for glycemic increases exceeding 2 mmol/L.

Keywords: diabetes mellitus, contrast sensitivity, visual acuity, pseudophakia

Correspondence: Lindokuhle Majola
Department of Health, Ugu District, PO Box 951, Hibberdene, Port Shepstone, 4220, South Africa
Tel +27 79 347 8540
Email lindokuhle.majola2@gmail.com

Alvin J Munsamy
Discipline of Optometry, School of Health Science, University of KwaZulu-Natal, Private Bag X54001, Durban, 4000, South Africa
Tel +27 31 260 7352
Fax +27 31 260 7666
Email MunsamyA@ukzn.ac.za

Introduction

The International Diabetes Federation (IDF) reported that diabetes mellitus (DM) is affecting three-and-a-half million South Africans and 366 million people globally, which is predicted to rise to 552 million by 2030.¹ The prevalence of DM is about 12.8% and 19 million in South African and Africa, respectively.² People living with diabetes mellitus (PDM) account for up to 20% of all cataract procedures, with this

increasing annually, evidence of the effect of glycemic changes in aphakic/pseudophakic PDM on vision is very limited. Previous studies^{3–12} have found changes on psychophysical measurement of visual function in phakic PDM limited to no studies on aphakic and pseudophakic PDM, respectively. Thus the impact of glycemic changes in pseudophakic PDM on vision should be a concern to inform safety practices on activities of daily living that include driving; reading, etc in society.

PDM complain of transient subjective visual disturbances, such as difficulty in reading or driving and blurred vision whilst using their spectacles, are not uncommon in daily clinical practice, due to fluctuating blood glucose level (BGL).^{12,13} The measurement of visual acuity (VA) and contrast sensitivity (CS) clinically accounts for these visual disturbances and are regarded as psychophysical measurements of vision.¹⁰ Since the nineteenth century fluctuating BGL has been known to cause transient visual changes in phakic PDM while little is known on aphakic and pseudophakic PDM.^{14,15} Pseudophakia refers to the implantation of an artificial intraocular lens (IOL) after the natural eye lens has been removed.¹⁶ CS is the ability of the visual system to realize differences between objects and background at finest detail.¹¹ In PDM, CS may be reduced even before the development of diabetic retinopathy and even when the VA is undisturbed. Hence measuring CS may be a useful tool for early detection of abnormalities in retinal function in PDM.¹¹

The purpose of this study was to show the effect of hyperglycemia on psychophysical measurements of visual function, including VA and CS in pseudophakic PDM. No studies on pseudophakic PDM have compared the effect of glycemic changes on psychophysical measurements. The study can alert eye practitioners of the significance or lack thereof of blood sugar level changes in pseudophakia and manage patients by alerting them to its acute influence on their vision.

Methods

This was an observational study using a case-control approach (quasi-experimental), quantitative study using a pretest–posttest approach. The study was conducted at Gamalakhe community health centre (CHC) located in Gamalakhe township. The eye clinic is situated in a community area where it is the first point of access for eye care services. A nonprobability convenience sampling technique was used to access the participants for this study from the clinic population that comprise of pseudophakic

PDM. A sample of 67 eyes of pseudophakic PWDM and 60 eyes of pseudophakic PDM comprised control and experimental groups for the study, respectively. Pseudophakic PDM were divided into two groups of people diagnosed with DM for more than 10 years and less than 10 years.

Selection Criteria

The study included pseudophakic people with and without DM who had a best corrected VA (BCVA) of 0.2 logMAR (Snellen equivalent 6/9). Participants who had ocular disorders such as corneal disease or surgery or posterior capsular opacification (PCO) and retinopathy were excluded. Participants with mild nonproliferative diabetic retinopathy to no retinopathy, weighing between 60 kg and 150 kg were included in the study.

Screening

The study commenced with a screening phase to ensure that participants satisfied the selection criteria for the study. A brief history was conducted before any testing to gather basic demographic data, ocular history and general health status. VA measurements were taken (with and/or without prescription glasses) to ensure the participants meet the minimum criteria for BCVA of 0.2 logMAR or better. A subjective refraction was administered to account for uncorrected refractive error to improve BCVA to satisfy the inclusion criteria. Near VA was measured with the prescription spectacles. Ophthalmoscopy and slit lamp biomicroscopy were performed to rule out ocular pathology that may have contaminated the psychophysical visual function test results and ultimately the research findings.

Data Collection

A pilot study using five pseudophakic PDM and five pseudophakic PWDM was performed to determine if changes in BGL causes changes in VA and CS, and if so to observe the average time and change in BGL to cause these visual changes. The pilot study was also conducted to determine the time it would take for each weight to reach a stable BGL postprandial. Ten participants that satisfied the inclusion criteria from screening phase were involved in the pilot study. Initial visual measurements which included VA and CS were measured for preprandial BGL and repeated for postprandial BGL and then compared. This showed it took 10 min for BGL to increase postprandial measurements informing the choice of visual measurements taken every 10 min until two consecutive

readings of BGL were unchanged at which point visual measurements stopped for both groups of pseudophakic PDM and PWDM for the main study. Pretest and posttest visual measurements were obtained preprandial and postprandial respectively. Figure 1 shows the overview of the data collection process for the main study.

Procedure

Hemoglucotest Measurements (Accu-Chek Active) for Glycemic Changes

The procedure involved pricking the index finger and inserting the blood on a glucose meter strip which was already inserted into the machine (Accu-chek active). The results were shown on the screen within 10 to 20 seconds and were recorded as preprandial and postprandial glyce-mic measurements. Postprandial BGL was measured until the participant reached peak BGL based on their weight and metabolism, measurements were stopped based on the results of the pilot study. Studies done by found Accu-chek hemoglucotest to be very reliable and repeatable even for self-monitoring of PDM.^{17–19}

LogMAR Visual Acuity Measurements (Bailey–Lovie Chart)

Distance and near VA were measured for each eye at 4 m and 40 cm using the logMAR VA chart, without and with the prescription in a normal room illumination (500 lux), respectively. To ensure uniformity, the same clinician obtained measurements. A line scoring method was used to determine the visual acuity of participants. The logMAR value of the best line read monocular was recorded and the number of letters read in the next row was multiplied by 0.02 and subtracted from the logMAR value of the best line completely read. Contrarily, when

letters were missed on a line, the number of the letters was multiplied by 0.02 and added to the acuity.²⁰

Contrast Sensitivity Measurements (Mars Chart)

CS was measured at 50 cm using the Mars chart while the participant had their best corrected near prescription for each eye.⁹ The participant was asked to read the letters from left to right across each line of the chart which was uniformly illuminated to ensure the best results. The participant was encouraged to guess the letters when they report that letters were faint. The last letter that the participant read was scored by subtracting 0.04 for every missed letter. The threshold acuity was recorded when two consecutive incorrect letters were read.

Ethical Considerations

Ethical permission was obtained before commencement of the study from the relevant authorities. The participants of this study each were given an information document and a consent form. The information document enlightened the participant about what the study entailed, while the consent form ensured the utmost confidentiality of all information gathered from the participant as well as the freedom to withdraw from the study. The tenets of the Declaration of Helsinki were observed throughout the study.

Statistical Analysis

Descriptive statistics such as frequencies and percentages were used to summarize categorical data. Measures of central tendency, mean and median, and measures of dispersion such as standard deviation and interquartile ranges were calculated for numerical variables. The Kolmogorov–Smirnov test was first used to assess distribution of data. The Kruskal–Wallis test was used to compare changes in

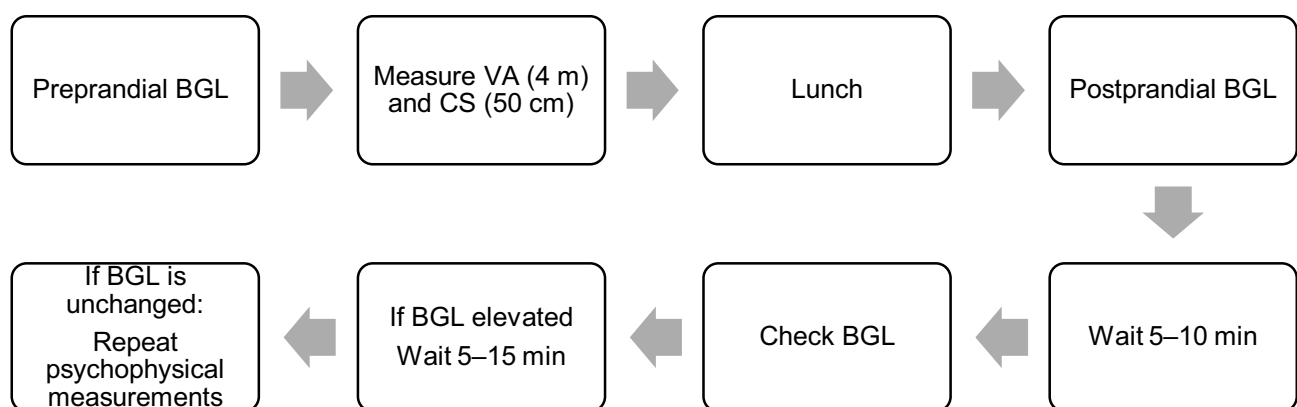


Figure 1 Flow chart demonstrating data collection process for psychophysical measurements.

glycemia for each group. The Wilcoxon signed rank test was used to test for pre- and postprandial CS and VA for each group. The Mann–Whitney *U*-test was used to compare these between pseudophakic PDM and PWDM. The effects of glycemic changes on visual functions were assessed using the multivariate linear regression analysis. A *p*-value less than 0.05 was considered statistically significant. All analysis was completed using SPSS version 25.

Results

A total of 100 African participants, 50 pseudophakic type 2 PDM none of whom were on insulin and 50 pseudophakic PWDM participated in this study. Sixty and 67 eyes were admitted for pseudophakic PDM and pseudophakic PWDM, respectively. Table 1 shows the mean age, weight and gender profiles of participants, the glycemic characteristics and the duration of diabetes for the experimental and control groups.

The mean change values for BGL, CS, and logMAR VA for pseudophakic PDM and PWDM for preprandial and postprandial measurements are given in Table 2. The mean change in CS for 2 mmol/L of hyperglycemia was 0.01 ± 0.10 log units ($p=0.23$) for pseudophakic PDM. The mean change in distance and near acuity was 0.01 ± 0.04 log units ($p=0.25$) and 0.002 ± 0.01 log units ($p=0.32$), respectively for pseudophakic PDM. These changes were all not statistically significant when compared with pseudophakic PWDM using the independent *t*-test and Mann–Whitney *U*-test.

Table 3 shows that when pseudophakic PDM who had DM for more than 10 years were compared to those who had DM for less than 10 years, there was no statistical significant effect on the change in CS and VA for hyperglycemia.

The effects of glycemic changes on visual functions was assessed using the multivariate linear regression analysis and is shown in Figure 2. This revealed no significant associations for glycemic changes and CS (A), distance visual acuity (B) and near visual acuity (C) for both PDM and PWDM.

Figure 2A shows a statistically insignificant correlation coefficient $\beta = -0.057$ (95%CI: -0.007 ; 0.005), $p=0.663$ and $\beta = -0.077$ (95%CI: -0.014 ; 0.007), $p=0.538$ in pseudophakic PDM and PWDM, respectively was observed between changes in BGL as well as changes in CS.

Figure 2B shows a statistically insignificant correlation coefficient $\beta = -0.044$ (95%CI: -0.013 ; 0.009), $p=0.737$ and $\beta = 0.512$ (95%CI: -0.004 ; 0.009), $p=0.538$ in pseudophakic PDM and PWDM, respectively was observed between changes in BGL as well as changes in distance VA.

Figure 2C shows a statistically insignificant correlation coefficient $\beta = 0.114$ (95%CI: -0.002 ; 0.005), $p=0.387$ and $\beta = -0.143$ (95%CI: -0.023 ; 0.006), $p=0.249$ in pseudophakic PDM and PWDM, respectively was observed between changes in BGL as well as changes in near VA.

Discussion

The study sought to assess the effects of glycemic changes on VA and CS in pseudophakic PDM. There were no statistically significant differences on VA and CS with hyperglycemia. Further to this, there was no statistically significant difference when pseudophakic PDM was compared to the pseudophakic PWDM. This observation occurred for hyperglycemic changes of 2.06 mmol/L in pseudophakic PDM and 1.08 mmol/L seen in pseudophakic PWDM. However, CS was statistically reduced in pseudophakic PDM who were diagnosed with DM for over 10 years compared to under 10 years.

CS changes were statistically similar between the two groups. This was in agreement with Ghafour et al⁹ and Andrade et al¹⁰ who found similar results in phakic PDM and PWDM. Acute hyperglycemic changes in phakic PDM are often associated with transient subjective visual disturbances, and CS testing is used to assess functional visual disturbances.¹³ It was found that acute hyperglycemic changes had no effect on CS in pseudophakic PDM

Table 1 Participant Characteristics of the Study

Group	N	Mean Age $\pm$ SD (Years)	Gender Distribution (N)		Mean Weight (kg)	Duration of DM (Years)		Mean Waiting Time (min)	Mean Glycemia (mmol/L)	
			F	M		<10	>10		Preprandial	Postprandial
PDM	60	61.33 $\pm$ 9.65	28	22	94.77 $\pm$ 22.20	35	25	24.62 $\pm$ 6.20	7.45 $\pm$ 2.60	9.44 $\pm$ 2.64
PWDM	67	69.55 $\pm$ 9.01	26	24	76.75 $\pm$ 14.75	n/a		23.13 $\pm$ 7.30	5.24 $\pm$ 0.90	6.34 $\pm$ 0.99
Total	127	65.67 $\pm$ 10.15	54	46	85.26 $\pm$ 20.65	35	25	23.83 $\pm$ 6.82	6.28 $\pm$ 2.19	7.80 $\pm$ 2.48

Table 2 The Effect: Hyperglycemic Changes on Psychophysical Measurements in Pseudophakic People with DM (PDM) and Pseudophakic without DM (PWDM)

Group	N (Eyes)	Mean Change Hyperglycemia $\pm$ SD (mmol/L)	t-Test	Kruskal-Wallis Test	Mean Change (+) CS $\pm$ SD (Log Units)	Wilcoxon Sign Ranked	t-Test	Mean Change (+) Distance LogMar Acuity $\pm$ SD	Wilcoxon Sign Ranked	Mann-Whitney U-Test	Mean Change (+) Near LogMar acuity $\pm$ SD	Wilcoxon Sign Ranked	Mann-Whitney U-Test
PDM	60	2.06 $\pm$ 1.35	$p<0.05$	$p=0.350$	0.01 $\pm$ 0.10	$p=0.23$	$p=0.27$	0.01 $\pm$ 0.04	$p=0.25$	$p=0.45$	0.002 $\pm$ 0.01	$p=0.32$	$p=0.13$
PWDM	67	1.08 $\pm$ 0.47		$p=0.291$	0.002 $\pm$ 0.02	$p=0.19$		0.001 $\pm$ 0.01	$p=0.32$		0.01 $\pm$ 0.03	$p=0.06$	

Notes: Mean change: posttest minus pretest; positive (+) implies increase.

Table 3 The Effect of the Duration of DM for Hyperglycemic Changes on Psychophysical Measurements in Pseudophakic People with DM

Duration (Years)	N (Eyes)	Mean Change Hyperglycemia (mmol/L)	Mean CS	Independent t-Test	Mean Change CS (Log Unit)	Independent t-Test	Mean Change (+) LogMar Acuity(D)	Independent t-Test	Mean Change (+) LogMAR Acuity (N)	Independent t-Test
<10	35	1.82 $\pm$ 0.93	1.19 $\pm$ 0.25	$p<0.001$	-0.006 $\pm$ 0.03	$p=0.10$	0.009 $\pm$ 0.04	$p=0.08$	0.003 $\pm$ 0.017	$p=0.09$
>10	25	2.25 $\pm$ 1.15	0.83 $\pm$ 0.81		+0.002 $\pm$ 0.008		0.004 $\pm$ 0.05		0.0000 $\pm$ 0.000	

Notes: Mean change: Posttest minus pretest; positive (+) implies increase; minus (-) implies decrease.

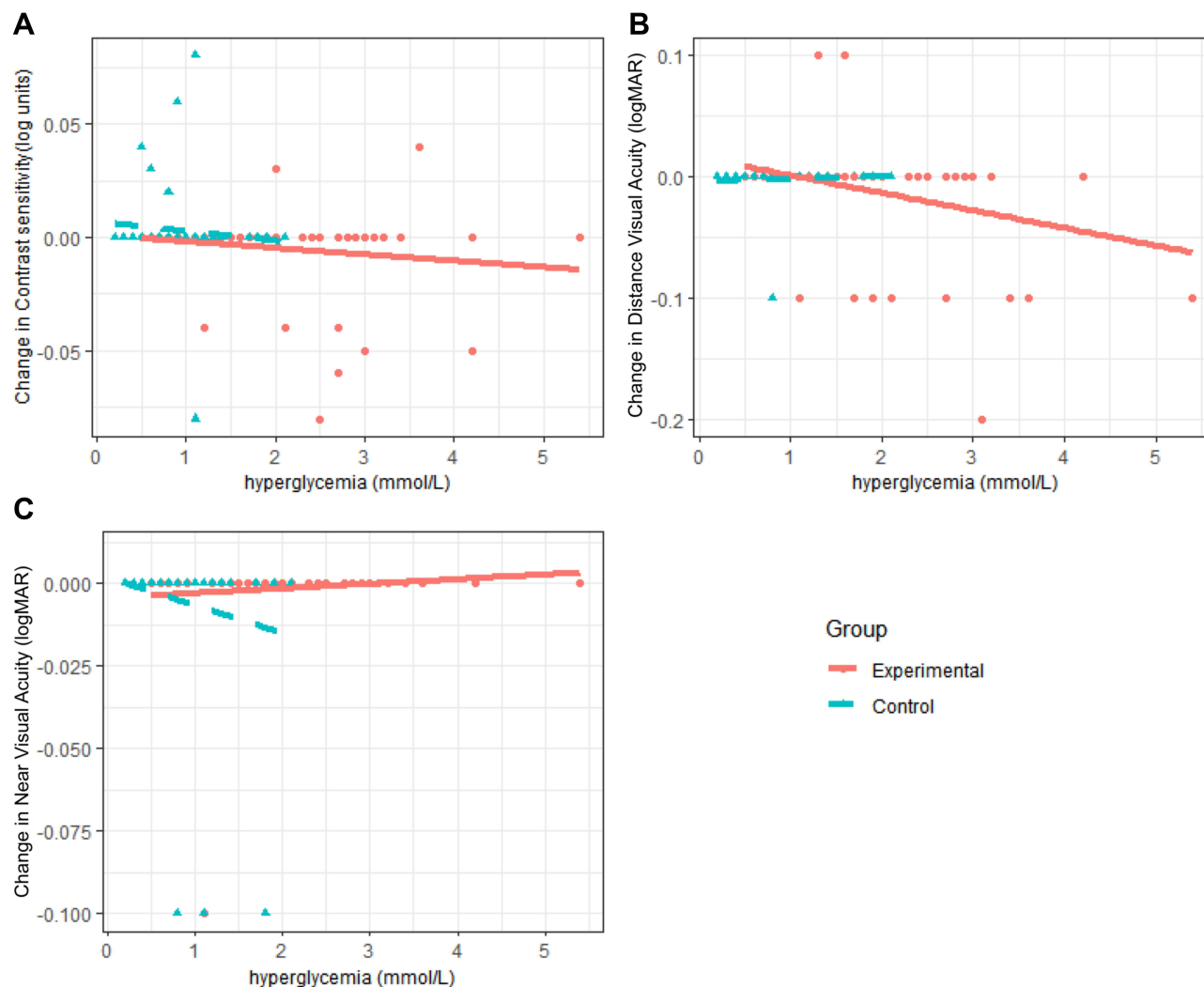


Figure 2 The association of hyperglycemia (independent variable) with psychophysical visual measurements (dependent variable) in pseudophakic PDM (diabetics) and PWDM (non-diabetics). **(A)** Experimental: $\beta = -0.06$ (95%CI: -0.007 ; 0.005), $p = 0.66$; control: $\beta = -0.08$ (95%CI: -0.014 ; 0.007), $p = 0.54$. **(B)** Experimental: $\beta = -0.04$ (95%CI: -0.013 ; 0.009), $p = 0.74$; control: $\beta = 0.51$ (95%CI: -0.004 ; 0.009), $p = 0.54$. **(C)** Experimental: $\beta = 0.11$ (95%CI: -0.002 ; 0.005), $p = 0.387$; control: $\beta = -0.143$ (95%CI: -0.023 ; 0.006), $p = 0.25$.

and PWDM. In contrast, studies (without retinopathy) on phakic PDM acute glycemic changes resulted in poorer CS.^{6,9} The present study results showed that acute glycemic changes in pseudophakic PDM do not cause acute subjective visual disturbances.

A mean CS of 0.83 ± 0.81 log units and 1.19 ± 0.25 log ($p < 0.001$) units was found in pseudophakic PDM and who had had DM for more than 10 years and less than 10 years, respectively. This shows that the duration of DM significantly affects the CS in pseudophakic PDM after 10 years. A study conducted by Noticewala and Shastri⁷ found no association between CS and the duration of DM in PDM having diabetic duration of less than 10 years. This was in disagreement with Mangouritsas et al¹³ who found no difference between

the duration of DM and CS in phakic insulin-dependent PDM. However, a later study by Rashmi et al¹¹ agreed with our study and found that phakic PDM with DM for over 10 years had lower CS compared to phakic PDM who have had DM for less than 10 years. In pseudophakic PDM, CS may be reduced even before the development of diabetic retinopathy in the presence of normal VA. Hence measuring CS may be a useful tool for early detection of abnormalities in retinal function in PDM.¹¹ This may be supported by the findings of the sub-group analysis that showed CS changes between DM (>10 years) and DM (<10 years). The present study suggests that the duration of DM may affect CS, resulting in poorer CS in pseudophakic PDM who have been diagnosed with DM for over 10 years.

A mainstream estimation of visual capacity is VA in light of the fact that the test is effortlessly regulated.¹² Hyperglycemic changes in pseudophakic PDM and PWDM did not significantly affect distance and near VA, this was in agreement with a study done by Giusti et al²² who found similar results on phakic PDM. However, studies done on phakic PDM found that acute glycemic changes affect distance VA whether in a hyper- or hypoglycemic state.^{10,18} Wiemer et al²² conducted a study on phakic PWDM and found a reduction in VA during hyperglycemia. However, this study²² was done on phakic non-diabetics compared to the present study which included pseudophakic non-diabetics. No previous studies have been found to be done at near vision. The present study also found no significant changes in distance VA and near best corrected VA of pseudophakic PDM who have been diagnosed with DM for less or more than 10 years. Furthermore, there is a paucity of studies comparing the duration of DM on VA either at distance and or at near vision.

A regression analysis showed a statistically insignificant negative correlation between hyperglycemia and change in CS. This is in agreement with Rashmi et al¹¹ who also found a positive correlation between CS and hypoglycemia in phakic PDM. A negative correlation was found between hyperglycemia and distance VA in pseudophakic PDM. Agardh et al²³ showed this in phakic PDM between distance VA and hyperglycemia although this was statistically insignificant in phakic PDM. It imperative to note that even though there is negative correlation between hyperglycemia and changes in psychophysical measurements of vision (distance VA and CS) in both phakic and pseudophakic PDM, these changes are statistically and clinically insignificant. For near visual acuity a positive correlation was found in pseudophakic PDM, however, the effects of hyperglycemia on near vision has not been investigated on phakic PDM.

Study limitations included the single BGL and measurements of vision. A recent HbA1c was not measured to determine if there is any correlation between HbA1c and psychophysical measurements of vision. In light of their individual dietary concerns, participants brought their own food for the study. The current study was limited to a single race group (African) with only type 2 DM. The glycemic changes for the experimental group was more than the control group, however, this may be related to the metabolism of non-diabetics and the ability to metabolize food. Unaided VA was measured at distance to determine if the changes

found in VA may not necessarily include the changes in refraction. However if the VA was very poor unaided, 6/60 and worse, changes will not be detected as the patients have blurred vision. Ebeigbe and Osaiywu²⁴ found a transient improvement in unaided as well as aided distance and near VA during hypoglycemia of phakic PDM, hence changes in aided and unaided VA show a similar trend during hypoglycemia of phakic PDM.

A larger sample size including both type 1 and type 2 DM is recommended for future studies. Studies attempting to raise the BGL more than 2 mmol/L may add value to the present study findings of unaffected CS and VA. The inclusion of HbA1c measurements may strengthen the BGL observation during the study. More studies that have a higher fluctuating blood glucose level are warranted. Studies with age and weight matched pseudophakic PWDM and diabetic pseudophakic are warranted. PDM The inclusion of other psychophysical measurements of vision such as color vision testing and glare sensitivity testing may strengthen the study findings. A cohort study where participants have repeated measurements of BGL and psychophysical measurement of vision would be able to better examine the relationship between BGL changes and psychophysical measurements of vision.

Conclusions

The present study highlights the effect of acute glycemic changes in pseudophakic PDM as well as pseudophakic PWDM on psychophysical measurements of visual function in VA and CS. Acute hyperglycemia of up to 2 mmol/L changes do not result in overall significant changes in VA and CS in both pseudophakic PDM and PWDM. However, the duration of DM may affect the CS in pseudophakic PDM without retinopathy who have had DM for more than 10 years. This was the first attempt to study the effects of acute glycemic changes on vision in diabetics and non-diabetics with pseudophakia. No other study has compared these two groups and this may help serve as a scientific basis for clinicians to inform the fluctuation of vision in pseudophakes during glycemic fluctuations up to 2 mmol/L. Further studies with hyperglycemia exceeding 2 mmol/L are recommended to confirm the findings of this study.

Ethics Approval and Consent to Participate

Biomedical Research Ethics Committee (BREC)

BREC Ref No: BE230/18

Affiliation: University of KwaZulu-Natal (UKZN)

A written consent to participate was obtained from all participants of the study.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

Disclosure

The authors reported no conflicts of interest in this work and declare that they have no financial or personal relationships which may have inappropriately influenced them in writing this article.

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