Research Square

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The Investigation Of The Effect Of Hyperglycaemic Changes On Psychophysical Measurements Of Visual Function In Pseudophakic People Living With Diabetes Mellitus.

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Research article

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

Posted Date: June 5th, 2020

DOI: https://doi.org/10.21203/rs.3.rs-30622/v1

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Abstract

Background

Phakic people living with diabetes mellitus (PDM) have been known to complain of transient subjective visual disturbances, however it has yet to be shown if this can extended to pseuodphakia as well. The measurement of visual acuity (VA) and contrast sensitivity (CS) forms part for these visual disturbances and is regarded as psychophysical measurements of vision. The purpose of this study was to show the effect of increasing blood glucose level (BGL) on visual acuity and contrast sensitivity in pseudophakic PDM.

Methods

This was quasi-experimental, quantitative study using a pretest-posttest approach. The study was conducted at Gamalakhe community health centre 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 pre-prandial and postprandial. VA was measured at distance (4 m) and near (40 cm) using LogMAR VA charts, CS was measured at 50 cm using Mars chart. Ethical permission was obtained before commencement of the study from Biomedical Research Ethics Committee (BREC) and KwaZulu-Natal Department of Health. The data collected was captured and subsequently analysed using the SPSS version 25. The Kruskal-Wallis Test and Wilcoxon Sign Ranked was used to compare changes within each group.

Results

Glycaemic changes observed had a mean increase of 2.06 ± 1.35 mmol/L and 1.08 ± 0.47 mmol/L in pseudophakia PDM and pseudophakic PWDM, respectively. A mean increase in CS of 0.01 ± 0.10 log units in PDM was found, however the independent T-Test showed this was insignificant between PDM and PWDM ($p = 0.27$). Mean increase in distance (0.01 ± 0.04 log units, $p = 0.25$) and near LogMAR VA (0.001 ± 0.01 log units, $p = 0.32$) for pseudophakic PDM was found, however the Mann-Whitney U-Test showed a statistically insignificant change $p = 0.45$ and $p = 0.13$ in distance and near VA respectively when compared to changes observed for pseudophakic PWDM.

Conclusions

Acute hyperglycaemic changes does not result in overall significant changes in visual acuity and contrast sensitivity in pseudophakic PDM for an increase in glycaemia of 2 mmol/L. However, the duration of DM may affect the CS in pseudophakic PDM without retinopathy who have had DM for greater than 10 years.

Background

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] People living with diabetes mellitus (PDM) account for up to 20% of all cataract procedures, with this increasing annually, evidence of the effect of glycaemic changes in aphakic/pseudophakic PDM on vision is very limited. Previous studies have found changes on psychophysical measurement of visual function in phakic PDM with limited to no studies on aphakic and pseudophakic PDM, respectively. Thus the impact of glycaemic 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.[2,3] The measurement of visual acuity (VA) and contrast sensitivity (CS) clinically accounts for these visual disturbances and is regarded as psychophysical measurements of vision. Since the nineteenth century fluctuating blood glucose level (BGL) has been known to cause transient visual changes in phakic PDM while little is known on aphakic and pseudophakic PDM.[4,5] Pseudophakia refers to the implantation of an artificial intraocular lens (IOL) after the natural eye lens has been removed.[6] The crystalline lens is metabolically active and requires nourishment in order to maintain its growth and transparency, while the IOL is not metabolically active but inert.[7]

Guisti et al.[8] (2003) found no statistically significant difference between VA and BGL changes in phakic PDM while Stavrou et al.[9] (2003) found a reduction in distance VA in phakic PDM during a hyperglycaemic state. In contrast studies[10–12] found that acute hypoglycaemia caused transient blurred vision in phakic PDM suggesting that despite the glycaemic changes in PDM, the VA changes. There is no clinical correlation between BGL and VA in phakic PDM.[8–12] Wiemer et al.[13] (2009) found no significant changes in the refractive properties of the eye and concluded that symptoms of blurred vision during hyperglycaemia are caused by small changes in high order aberration. The generally accepted view is that the diabetes-related short term fluctuations of VA are primarily caused by accumulation of sorbitol and fructose into the lens by the sorbitol pathway with a decreased lens refractive index following water influx.[14] No studies on pseudophakic PDM has compared the effect of glycaemic changes on VA.

CS is the ability of the visual system to realise differences between objects and background at finest detail.[15] 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.[15]

Ghafour, et al.[16] concluded that phakic PDM have poorer CS to people without diabetes mellitus (PWDM).[16] Di Leo et al.[17] then found that hyperglycaemia in phakic PDM showed a significant reduction in contrast threshold compared to phakic PWDM.[17] Recent studies found similar results with significant loss of CS clinically and statistically and also found that phakic PDM without retinopathy had lower mean monocular CS at all spatial frequencies than the phakic PWDM, but the difference only reached statistical significance in two out of 11 spatial frequencies tested, 15 and 30 cpd ($p < 0.05$).[9,18] CS can be used to grade and monitor the progression of diabetic retinopathy as there is a greater loss of CS in severe diabetic retinopathy. No studies on pseudophakic PDM has compared the effect of transient BGL changes on CS function.

The purpose of this study was to show the effect of hyperglycaemia on psychophysical measurements of visual function including VA and CS in pseudophakic PDM. The study was guided by the following questions:

- Does glycaemic changes have an effect on distance and near LogMAR visual acuity in pseudophakic people living with diabetes mellitus?
- Does glycaemic changes have an effect on contrast sensitivity in pseudophakic people living with diabetes mellitus using Mars CS chart?

Methods

This was a quasi-experimental, quantitative study using a pretest-posttest approach. The study was conducted at Gamalakhe community health centre (CHC), Eye clinic which is situated in a community area where this is a first point of access for eye care services. A non-probability convenience sampling technique was used to access the participants for this study, from the clinic population that comprise of pseudophakic-PDM. A sample of 50 pseudophakic PWDM and 50 pseudophakic-PDM comprised control and experimental groups for the study, respectively.

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 non-proliferative diabetic retinopathy to no retinopathy, weighing between 60 kg to 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. 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. 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 pre-prandial BGL and repeated for post-prandial BGL and then compared. This showed it took 10 minutes (min) for BGL to increase postprandial measurements informing the choice of visual measurements taken every 10 minutes 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. Pre-test and post-test visual measurements were obtained pre-prandial and post-prandial respectively. Figure 1 shows the overview of the data collection process for the main study.

Procedure

Haemoglucotest measurements (Accu-chek Active) for glycaemic 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 was shown on the screen within 10 to 20 seconds and was recorded as pre-prandial and post-prandial glycaemic measurements. Post-prandial 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 haemoglucotest to be very reliable and repeatable even for self-monitoring of PDM. [19–21]

LogMAR Visual Acuity Measurements (Bailey Lovie chart)

Distance and near VA were measured for each eye at 4 m and 40 cm using 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.[22]

Contrast Sensitivity Measurements (Mars chart)

CS was measured at 50 cm using Mars chart while the participant had their best corrected near prescription for each eye. 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 enlightens the participant about what the study entailed, while the consent form ensures the outmost 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 was observed throughout the study.

STATISTICAL ANALYSIS

Descriptive statistics such as frequencies and percentages were used to summarise categorical data. Measures of central tendency, mean and median, and measures of dispersion such as standard deviation and interquartile ranges was calculate for numerical variables. The Kolmogrov-Smirnov test was first used to assess distribution of data. The Kruskal-Wallis Test was used to compare changes in glycaemia for each group. The Wilcoxon Signed Rank Test was used to test for pre- and post-prandial CS and VA for each group. The Mann-Whitney U-Test was used to compare these between pseudophakic PDM and PWDM. The effects of glycaemic changes on visual functions was assessed using the multivariate linear regression analysis. A p-value less than 0.05 was considered statistically significant. All analysis was completed using the 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. Table 1 shows the mean age, weight and gender profiles of participants, the glycaemic characteristics and the duration of diabetes for the experimental and control group.

The mean change values for BGL, CS and LogMAR VA for pseudophakic PDM and PWDM for pre-prandial and postprandial measurements are given in Table 2. The mean change in CS for 2 mmol/L of hyperglycaemia 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 was 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 hyperglycaemia.

The effects of glycaemic changes on visual functions was assessed using the multivariate linear regression analysis and is shown on Fig. 2. This revealed no significant associations for glycaemic 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 β=-0.057 (95% CI: -0.007; 0.005), p = 0.663 and β=-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 β=-0.044 (95% CI: -0.013; 0.009), p = 0.737 and β = 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 β = 0.114 (95% CI: -0.002; 0.005), p = 0.387 and β=-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 glycaemic changes on VA and CS in pseudophakic PDM. There were no statistically significant difference on VA and CS with hyperglycaemia. Further to this, there was no statistically significant difference when pseudophakic PDM was compared to the pseudophakic PWDM. This observation occurred for hyperglycaemic changes of 2.06 mmol/L in pseudophakic PDM and 1.08 mmol/L seen in pseudophakic PWDM. However CS were statistically reduced in pseudophakic PDM who were diagnosed with DM for over 10 years as compared to under 10 years.

Although statistically insignificant, the present study found that pseudophakic-PDM had reduced CS as compared to pseudophakic PWDM without retinopathy which may be of clinical value. This was in agreement with Ghafour et al.[16] and Andrade et al.[23] who found that similar results in phakic PDM and PWDM. 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.[15] Acute hyperglycaemic changes in phakic PDM is often associated with transient subjective visual disturbances, and CS testing is used to assess functional visual disturbances.[2] It was found that acute hyperglycaemic changes had no effect on CS in pseudophakic PDM and PWDM. In contrast, studies (without retinopathy) on phakic PDM acute glycaemic changes resulted in poorer CS. The present study results suggests that acute glycaemic changes in pseudophakic PDM may not cause acute subjective visual disturbances.

A mean CS of 0.83 log units and 1.19 log units was found in pseudophakic PDM and who had had DM for less than 10 years and more than 10 years respectively. This shows that the duration of DM significantly affect the CS in pseudophakic PDM. This was in disagreement with Mangouritsas et al.[2] who found no difference between the duration of DM and CS in phakic insulin-dependent PDM. However a later study by Rashmi et al.[15] agreed with our study and found that phakic PDM with DM for over 10 years had lower CS as compared to phakic PDM who have had DM for less than 10 years. The present study suggests that the duration of DM may affect CS, resulting in poorer

CS in type 2 non-insulin dependent phakic and 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.[3] Hyperglycaemic 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 al.[8] who found similar results on phakic PDM. However studies done on phakic PDM found that acute glycaemic changes affect distance VA whether in a hyper- or hypoglycaemic state.[10,18] Wiemer el al.[24] conducted a study on phakic PWDM and found a reduction in VA during hyperglycaemia. However this study[24] was done on phakic non-diabetes as compared to the present study which included pseudophakic non-diabetes. No previous studies have been found to be done at near. 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 over 10 years. Furthermore, there is a paucity of studies comparing the duration of DM on VA either at distance and or at near.

Although the regression analysis was insignificant, a negative correlation between hyperglycaemia and change in CS was found in pseudophakic PDM, implying hyperglycaemia resulted in a reduction in CS. This is in agreement with Rashmi et al.[15] who also found a positive correlation between CS and hypoglycaemia in phakic PDM. A negative correlation was found between hyperglycaemia and distance VA in pseudophakic PDM. Agardh et al.[25] showed this in phakic PDM between distance VA and hyperglycaemia although this was statistically insignificant in phakic PDM. It imperative to note that even though there is negative correlation between hyperglycaemia 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 hyperglycaemia 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. The current study was limited to a single race group (African) with only Type 2 DM. The glycaemic 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 metabolise 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 won't be detected as the patients are blurred. Ebeigbe et al.[26] found a transient improvement in unaided as well as aided distance and near VA during hypoglycaemia of phakic PDM, hence changes in aided and unaided VA shows a similar thread during hypoglycaemia 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. The inclusion of other psychophysical measurements of vision such as colour 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 glycaemic changes in pseudophakic PDM as well as pseudophakic PWDM on psychophysical measurements of visual function in VA and CS. Acute hyperglycaemic of up to 2 mmol/L changes does 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 greater than 10 years. This was the first attempt to study the effects of acute glycaemic 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 glycaemic fluctuations up to 2 mmol/L. Further studies with hyperglycaemia exceeding 2 mmol/L is recommended to confirm the findings of this study.

Abbreviations

BCVA
Best Corrected Visual Acuity
BGL
Blood Glucose Level
CS
Contrast Sensitivity
DM
Diabetes Mellitus
HbA1c
Glycated Haemoglobin
LogMAR
Logarithm of the Minimum Angle of Resolution
PDM
People Living With Diabetes Mellitus/Diabetics
PWDM
People Living Without Diabetes Mellitus/Non-Diabetics
VA
Visual Acuity

Declarations

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.

CONSENT FOR PUBLICATION

Not applicable

AVAILABILITY OF DATA AND MATERIALS

The datasets generated and/or analysed during the current study are not publicly available due individual privacy but are available from the corresponding author on reasonable request.

COMPETING INTERESTS

The authors declare that they have no financial or personal relationships which may have inappropriately influenced them in writing this article.

FUNDING

College of Health Science Scholarships, University of KwaZulu-Natal. The role of the funding body in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

AUTHORS' CONTRIBUTIONS

L.M. contributed towards the background, methods, results, discussion, conclusions as well as the final research presentation. A.J.M. was the project facilitator and supervisor.

ACKNOWLEDGMENTS

A University of KwaZulu-Natal (UKZN), Developing Research Innovation, Localisation and Leadership in South Africa (DRILL) fellow. DRILL, is a NIH D43 grant (D43TW010131) awarded to UKZN in 2015 to support a research training and induction programme for early career academics. The content is solely the responsibility of the authors and does not necessarily represent the official views of DRILL and the National Institutes of Health.

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Tables

TABLE 1. Characteristics of study population.

Group	N	Mean Age ±SD (years)	Gender distribution (n)		Mean Weight (Kg)	Duration of DM (years)		Mean Waiting Time (minutes)	Mean Glycaemia (mmol/L)	
			F	M		<10	>10		Pre-prandial	Postprandial
PDM	50	61.33 ±9.65	28	22	94.77±22.20	35	25	24.62±6.20	7.45±2.60	9.44±2.64
PWDM	50	69.55 ±9.01	26	24	76.75±14.75	n/a		23.13±7.30	5.24±0.90	6.34±0.99
Total	100	65.67 ±10.15	54	46	85.26±20.65	35	25	23.83±6.82	6.28±2.19	7.80±2.48

TABLE 2. The effect hyperglycaemic changes on psychophysical measurements in pseudophakic PDM and PWDM

Group	N (eyes)	Mean Change Hyperglycaemia ±SD (mmol/L)	Kruskal-Wallis Test	Mean Change (+) CS ±SD (log units)	Wilcoxon Sign Ranked	T-Test	Mean Change (+) Distance LogMar acuity ±SD	Wilcoxon Sign Ranked	Mann-Whitney U Test	Mean Change (+) Near LogMar acuity ±SD	Wilcoxon sign ranked	Mann-Whitney U Test
PDM	60	2.06±1.35	p=0.350	0.01±0.10	p=0.23	p=0.27	0.01±0.04	p=0.25	p=0.45	0.002±0.01	p=0.32	p=0.13
PWDM	67	1.08±0.47	p=0.291	0.002±0.02	p=0.19		0.001±0.01	p=0.32		0.01±0.03	p=0.06	

Mean change: Post-test minus pre-test; positive (+) implies increase

TABLE 3. The effect of the duration of DM on psychophysical measurements in pseudophakic PDM.

N (eyes)	Mean change hyperglycaemia (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
35	1.82±0.93	1.19±0.25	p<0.001	-0.006±0.03	p=0.10	0.009±0.04	p=0.08	0.003±0.017	p=0.09
25	2.25±1.15	0.83±0.81		+0.002±0.008		0.004±0.05		0.0000±0.000	

Mean change: Post-test minus pre-test; positive (+) implies increase; minus (-) implies decrease

Figures

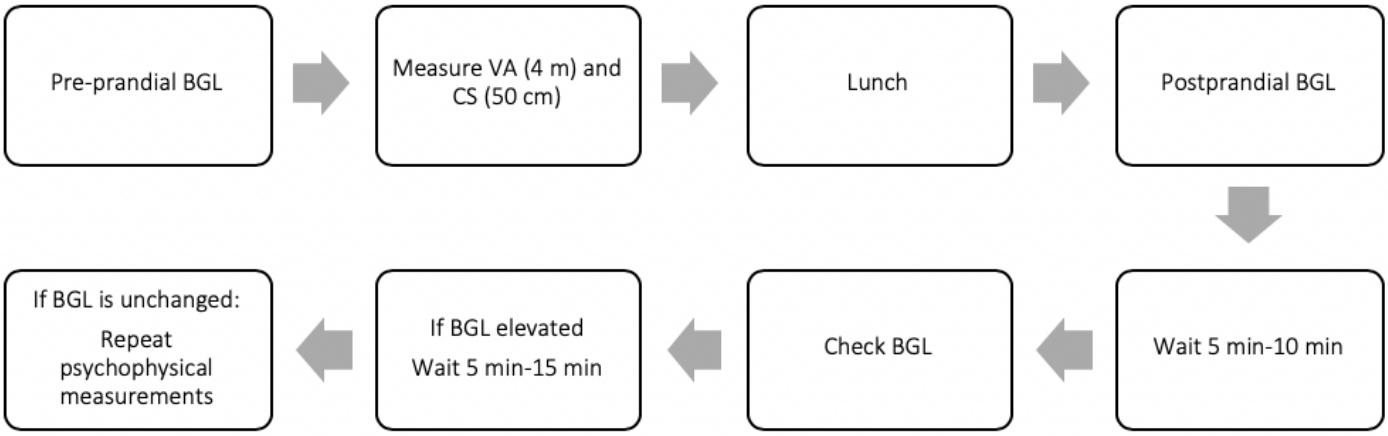

Figure 1

Flow chart demonstrating data collection process for psychophysical measurements.

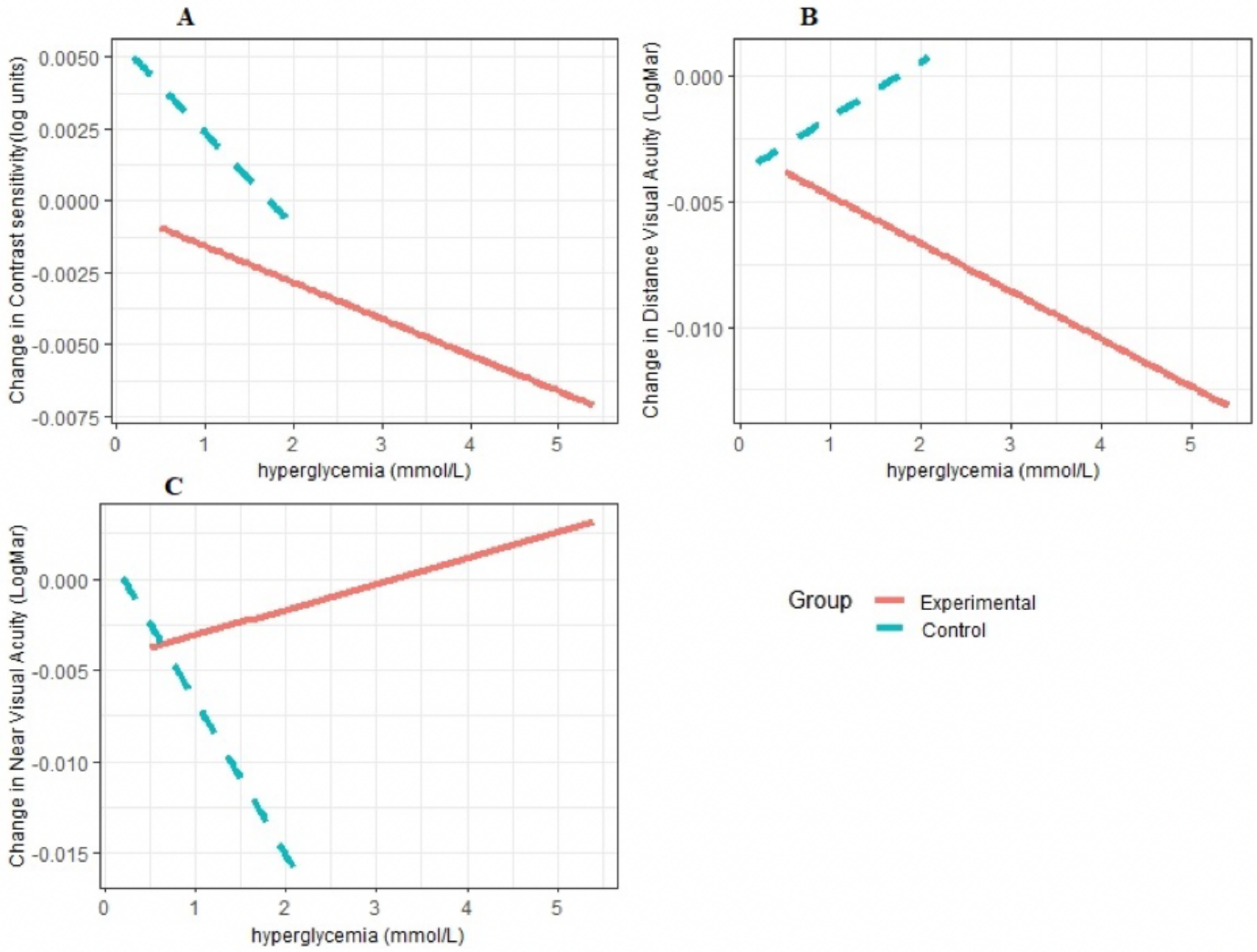

Figure 2

The association of hyperglycaemia with psychophysical visual measurements in pseudophakic PMD and PWDM.