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Eye Focusing Ability Can Predict Glycated Hemoglobin Level of Type-1 Diabetes Patients

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ABSTRACT

Background and Aims: Glycated Hemoglobin (HbA1c) is crucial for diagnosing and monitoring diabetes. However, current tests are complex, invasive, costly, and often met with low compliance. This study aimed to find whether simple clinical, noninvasive measures of the ocular accommodation function may predict the glycated hemoglobin results in type-1 diabetes mellitus.

Methods: In a single-examiner-blind study, Near Point of Accommodation (NPA) and Lag of Accommodation (LoA) were compared between type-1 diabetes patients and controls. NPA was measured by the push-up-to-blur method, LoA by the Monocular Estimation Method (MEM) retinoscopy, and glycated hemoglobin was recorded with a Point-of-Care (POC) HbA1c analyzer. The independent *t*-test was employed to assess the difference in means between groups. Correlational analysis was conducted to examine the relationship between HbA1c levels and accommodative measures. Additionally, Structural Equation Modeling (SEM) was utilized to evaluate the interrelationships among variables and to determine the extent to which the model could explain the variance in HbA1c.

Results: Diabetic patients had a receded mean NPA (15.16 ± 4.53 cm) compared to controls (9.48 ± 1.43 cm; $p < 0.001$). When converted to the Amplitude of Accommodation (AoA) in diopters (D), the mean AoA was lower in diabetics (6.6 ± 2.28D) than in controls (10.55 ± 1.52D; $p < 0.001$). Diabetics had a higher mean LoA (0.983 ± 0.74D) than controls (0.156 ± 0.44D; $p < 0.001$). After controlling for age ($\beta = -0.167$, $p = 0.017$) and the duration of diabetes mellitus (DM) ($\beta = 0.665$, $p = 0.051$), the SEM analysis indicated that the NPA was a significant predictor of HbA1c levels, with a path coefficient estimate (β) of 0.345 ($p < 0.001$). In contrast, the LoA did not significantly predict HbA1c levels ($\beta = 0.005$, $p = 0.993$). The model explained 38.7% of the variance in HbA1c, indicating a satisfactory fit to the experimental data.

Conclusions: The study found eye accommodation was significantly affected in recent type-1 diabetes patients, indicating its sensitivity to diabetes. SEM using these ocular measures accounts for one-third of HbA1c variance. Thus, accommodative function assessments could be a simple, noninvasive, and cost-effective method for evaluating HbA1c levels. LoA is not a good predictor of HbA1c.

Abbreviations: AOA, amplitude of accommodation; DC, diopter cylinder; DM, diabetes mellitus; DS, diopter sphere; FBS, fasting blood sugar; HbA1c, glycated hemoglobin; LoA, lag of accommodation; NPA, near point of accommodation; NPC, near point of convergence; RAF, royal airforce.

Bright Vandyke Okyere and Benedict Ayobi are co-first authors and contributed equally to this study.

Summary

- Glycated hemoglobin (HbA1c) is an essential test for diagnosing and monitoring diabetes.
- However, current tests for monitoring blood sugar are complex, costly, invasive, and often met with low compliance.
- There is, therefore, a need to develop alternative, non-invasive, and less costly means of monitoring blood sugar levels.
- Near point of accommodation, NPA significantly predicted blood sugar levels (HbA1c) in type-1 diabetes patients.
- Thus, accommodative function assessments could be a simple, noninvasive, and cost-effective method for evaluating HbA1c levels.

1 | Introduction

Diabetes Mellitus (DM), or diabetes, is a group of metabolic diseases marked by prolonged hyperglycemia due to defects in insulin secretion, action, or both [1]. It is typically identified by persistent hyperglycemia, with Fasting Blood Sugar (FBS) levels over 7.0 mmol/L or 110 mg/dL or Glycated Hemoglobin (HbA1c) over 6.5% [2]. Diabetes mellitus (DM) is a rapidly escalating epidemic, with the International Diabetes Federation (IDF) reporting 537 million adults affected in 2021, a figure projected to surge to 800 million by 2045 [3]. Estimated DM prevalence varies geographically, with urban areas of Sub-Saharan Africa showing higher age-specific levels than most Western European countries [3]. Africa's diabetes prevalence is projected to more than double from 25 million to 60 million by 2050 [4]. There are three main types of diabetes: type-1, type-2, and gestational. Type-1 diabetes, representing 5%–10% of global cases and is more common in children, is caused by an autoimmune response that destroys pancreatic beta-cells, leading to insulin loss and severe hyperglycemia. Type-2 diabetes, characterized by insufficient insulin secretion or reduced cell utilization, is caused by peripheral insulin resistance, impaired hepatic glucose regulation, or declining ß-cell function, leading to inadequate insulin production. Gestational diabetes occurs in pregnancy, usually due to inadequate expansion of β-cells to meet the increased demand for insulin secretion in pregnancy [5, 6].

There is an urgent need to scale up efforts to reduce the prevalence of existing cases of diabetes. Early identification and monitoring of sustained hyperglycemia are critical to effective management [7–13]. Several tests and procedures have been used to diagnose diabetes. These include FBS, HbA1c, and Glucose Tolerance Tests [14–16]. These tests are effective at predicting plasma sugar concentration. In spite of the availability of these tests, there are still some drawbacks to effective diabetes management. The cost of acquiring the test kits, reagents, and the human resources to operate the equipment may hinder timely diagnosis and management. In Ghana, for example, the mean cost of managing one diabetes case annually was 540 cedis (equivalent to $194 as of 2021) [17]. One study found that the cost of a glucometer and a test strip, ranging between $15 and $121 and $1.2/strip, respectively, posed significant challenges to diabetes management [18]. Additionally, most of these tests are invasive (involve pricking with a needle to obtain blood samples), reducing patient compliance with these tests [19]. Due to these drawbacks, there is interest in determining alternate measures capable of predicting blood sugar control by diabetes patients [20].

The effect of long-standing hyperglycemia on peripheral organs has been well documented. In the eye, persistent uncontrolled blood sugar concentration has been associated with secondary pathophysiologic changes in various tissues, affecting optical quality and retinal sensitivity in patients with diabetes [21]. Ocular accommodation is the crystalline lens's ability to adjust its shape for near focus, achieved through ciliary muscle contraction, increasing the eye's dioptric and refractive power [22]. Two common clinical tests for assessing the ocular accommodation function are the Amplitude of Accommodation (AoA) and the Lag of Accommodation (LoA). AoA is the maximum increase in the eye's refractive power, achieved by adjusting the shape of the crystalline lens to focus on near objects [23]. The Near Point of Accommodation (NPA) is the closest clear focus point, typically the inverse of the AoA in centimeters [23, 24]. LoA refers to the discrepancy between the eye's accommodative response and the "actual" demand for accommodation, often resulting in a focus point behind the intended target. Recent studies indicate that diabetes impacts the ocular accommodative system through changes in lens glucose metabolism and ischemic hypoxia of the oculomotor nerve and ciliary muscles [23–28]. Hence, accommodative function is often affected early in diabetes, preceding ocular complications like cataracts, diabetic retinopathy, and associated neuro-ophthalmic disorders [29–31]. In previous studies, we showed that the ocular accommodation functions correlate positively with the fasting blood sugar levels, and adequate control of the blood sugar could reverse near-visual problems in diabetes [29, 30]. This study explored whether the ocular accommodative functions in diabetes patients correlate with and could predict HbA1c, a reliable indicator of average blood sugar levels over the past 3 months [32]. The study outcome, therefore, could impact factors including cost, time, and patient safety in the context of diabetes monitoring.

2 | Materials and Methods

The study was a hospital-based, cross-sectional case-control study. The study was conducted at Mzuzu Central Hospital (MCH) Diabetic Clinic from January 2020 to March 2020. The diabetes subjects were between 15 and 35 years old. Age-matched healthy subjects were included as controls. A minimum sample size of 40 participants per group was predetermined as appropriate for conducting multiple linear regression with up to four predictors. This is based on an alpha of 0.05, a power of 0.80, and an effect size of 0.35 in the population [33].

Approval for this study was granted by the Faculty of Health Sciences Research Committee at Mzuzu University; report

number REC/FHS/20/013. Informed consent was obtained from the participants or their guardians if subjects were under 18. Patient confidentiality and privacy were respected using assigned numbers rather than participant names. The study followed the Declaration of Helsinki guidelines for human subject research.

MCH is a referral hospital for the Northern region of Malawi. The diabetic clinic of MCH has a population of about 2000 diabetic patients, of whom 500 are patients living with Type 1 DM (based on the C-peptide levels tested) [34]. A systematic sampling technique was used to recruit participants from the diabetic clinic at the hospital (45 diabetic patients and 45 controls). Patients at the diabetic clinic were randomly assigned numbers before the study day. Patients with odd numbers who satisfied the inclusion criteria were recruited during the study. Inclusion criteria for diabetic subjects were patients between 15 and 35 years with normal anterior segment and presenting visual acuity (PVA) better than or equal to 6/6. Exclusion criteria included the presence of ametropia worse than ±0.50 DS/DC and evidence of active ocular pathologies such as moderate to severe diabetic retinopathy, glaucoma, uveitis, ocular trauma, and cataracts. Additionally, subjects using systemic drugs that have a known effect on accommodation and the peripheral nervous system were excluded. Patients with type-2 diabetes and diabetic pregnant women were also excluded from the study. Participants with significantly receded Near Point of Convergence (NPC), especially presbyopes, were excluded.

2.1 | Examination Protocol

To rule out any comorbid pathological conditions that could impact the study's outcome, subjects recruited first underwent comprehensive ocular examinations. The tests carried out included distance Visual Acuity (VA) using the Logarithm of the Minimum Angle of Resolution (logMAR) chart, examination using the slit lamp biomicroscope, fundus examinations using the binocular indirect ophthalmoscope, and subjective non-cycloplegic refraction, as well as binocular vision assessment. Other ocular measures, such as NPA and LoA, were measured and recorded. Patient demographics, as well as the duration of diabetes, were recorded.

2.2 | Measuring HbA1c Level

Glycated hemoglobin (HbA1c) levels were measured in this study. HbA1c, measures the average sugar level over a 3-month period [32]. It is, therefore, a stable measure of average blood sugar concentration and predicts the actual blood sugar levels better than fasting blood sugar. HbA1c was measured by a single laboratory technician using an SD A1cCARE analyzer (SD Biosensor Inc., Korea). Khadanga et al. [35] reported comparable results using the SD A1cCARE analyzer and High-Performance Liquid Chromatography (HPLC). They, therefore, reported that the SD A1cCARE analyzer is a better alternative to HPLC [35]. According to the manufacturer's instructions, a drop of capillary blood sample was obtained by pricking the disinfected fingertip with a lancet. Using a 5 μL pipette, a drop of the blood was taken and mixed with about 200 μL of buffer solution. The mixture was shaken thoroughly in a test tube. Using a 200 μL pipette, 200 μL of the blood-buffer mixture was collected and applied to the test panel of the glucometer. The plasma glucose concentration was read after 3 min [3] and presented as a percentage (%). All the readings were done in the morning (between 7 a.m. and 10 a.m.) by one laboratory technician.

2.3 | Measuring Accommodative Functions

The NPA was measured monocularly (right eye only) using the subjective push-up-to-blur method. The push-up-to-blur method is a simple clinical test requiring minimal instruction/training. This was done over the subjects' corrected distance spectacle prescription, if any, determined during the study by non-cycloplegic subjective refraction. The subjects were asked to read the N6 letters on the Royal Air Force (RAF) rule (CE 0120 HS Clement Clarke International, Harlow, United Kingdom) under optimal illumination. The RAF rule was set to zero and held horizontally about 40 cm (16 in.) from the patient's eye. The subjects were instructed to cover their non-tested (left) eye with their hand and asked to focus on the N6 line (target) of the rule with their eye being tested (right eye). The subjects were instructed to keep the target clear and report when it blurred. The endpoint was the first slight sustained blur, which was considered the point when the target could not be cleared after 2 or 3 s of viewing. The distance from the target to the spectacle plane was measured using the RAF rule as the NPA. It was then converted into diopters to get the AoA. The procedure was repeated twice to ensure accuracy; the average NPA was recorded. The monocular AoA was recorded in diopters.

LoA was tested by the Monocular Estimation Method (MEM). As described by Nguyen et al., the participants were positioned 40 cm away from the examiner under normal room illumination. The participants were instructed to read the optotypes attached to the retinoscope head. At the same time, the examiner performed the tests by observing movement in the horizontal meridian of the right eye through the retinoscope. The accommodative response (lead or lag) was measured by neutralizing the "*against*" movement or "*with*" movement of the retinoscopic reflex by adding minus or plus lenses in front of the participant's eyes, respectively. The endpoint was reached when the examiner observed no movement after scoping the eyes [36].

2.4 | Data Analysis

The collected data were evaluated using the Statistical Package for Social Sciences software (SPSS, version 26). Results were represented as means (±SD) in tables. The difference between the diabetes patients and healthy controls was ascertained using the independent *t*-test. A p value less than 0.05 was considered statistically significant. Structural Equation Modeling (SEM) analyses were conducted in SPSS AMOS software (version 30). Maximum likelihood estimation was performed on path coefficients between observed variables.

TABLE 1 | Comparison of participants' characteristics and ocular accommodation measures between groups.

Characteristic	Diabetic group	Control group
Male *n* (%)	16 (17.8)	27 (30.0)
Female *n* (%)	29 (23.2)	18 (20.0)
Age (years)	27.4 ± 5.75	21.2 ± 4.70
Onset of diabetes (years)	1.8 ± 1.18	—
HBA1c (%)	10.43 ± 2.75	4.55 ± 0.50
Near point of accommodation (cm)	15.156 ± 4.53*	9.478 ± 1.43
Accommodative lag (D)	0.983 ± 0.74*	0.156 ± 0.44

Note: Data were presented as frequency or mean ± SD; difference between the diabetes group and control.
*$p < 0.001$.

3 | Results

3.1 | Demographic and Clinical Characteristics

The study included 90 participants: 45 diabetics (16 males and 28 females) and 45 age-matched healthy control subjects (27 males and 18 females). For all subjects, the ages ranged from 15 to 35 years. Table 1 presents the characteristics of diabetic and control subjects. The mean age of the diabetic and control subjects was 27.4 ± 5.75 years and 21.2 ± 4.70 years, respectively. The blood sugar level, HbA1c, in the diabetic subjects was significantly higher than in the age-matched controls (10.43% ± 2.75% vs. 4.55% ± 0.50%, respectively, $p < 0.001$). The mean duration of diabetes in the diabetic group was 1.8 ± 1.18 years.

3.2 | Difference in Accommodative Function Measures Between Groups

The independent *t*-test results indicated a significant recession in the NPA for diabetic subjects compared to controls (15.156 ± 4.53 cm vs. 9.478 ± 1.43 cm, respectively; $p < 0.001$; Table 1). Figure 1 further illustrates a marked age-related increase in NPA among diabetic subjects, in contrast to a gradual increase in controls, underscoring the influence of diabetes on NPA as a function of age. Also, a significantly elevated LoA was observed in diabetics compared to controls (0.983 ± 0.74D vs. 0.156 ± 0.44D, respectively; $p < 0.001$; Table 1). The LoA demonstrated a steep increase with age among diabetics, while among the controls, it exhibited a steady increase (Figure 2).

3.3 | Structural Equation Modeling of the Relationship Between HbA1c and NPA/LoA

The structural equation modeling (SEM) analysis was performed using AMOS to assess the impact of various predictors on HbA1c levels, as presented in Table 2 and Figure 3. While accounting for variables such as participants' age ($\beta = -0.167$; $p = 0.017$) and duration of diabetes mellitus (DM) ($\beta = 0.665$; $p = 0.051$), the SEM results revealed that the Near Point of Accommodation (NPA) was a significant predictor of HbA1c levels, with a path coefficient estimate (β) of 0.345 ($p < 0.001$). This finding indicates that an increase in NPA is associated with an increase in HbA1c levels. Conversely, the Lag of Accommodation (LoA) did not significantly predict HbA1c levels ($\beta = 0.005$; $p = 0.993$). The coefficient of determination (R^2) of 0.387 showed that the model predicted 38.7% of the measured HbA1c variance and adequately fit the experimental data. A partial correlation was performed to evaluate the relationship between HbA1c and NPA, or LoA, in the diabetes group. After adjusting for age and duration of diabetes, HbA1c showed a significant moderate positive correlation with NPA, $r[37] = 0.35$, $p = 0.020$), but not with LoA, $r[37] = 0.14$, $p = 0.364$ (Table 3).

4 | Discussion

Diabetes has become a disease of global importance. While several tests aimed at monitoring blood sugar control in diabetes have been developed to aid in early detection and effective management, they come with several challenges, as stated earlier. The development of an alternative procedure that is effective and less invasive to measure blood sugar will be a giant step in diabetes management. The lens of the human eye is an essential component of the total refractive system of the eye. It significantly contributes to the eye's refractive status by providing about 25D of the total refractive power of the eye [38]. The delicate arrangement of the crystalline protein fibers ensures the clarity and elasticity of the lens. Alterations in the structure and morphology of the lens result in changes in the eye's refractive status [39]. As reported by previous studies, diabetes impacts the morphology of the crystalline lenses and invariably affects accommodative function in a manner related to the blood sugar concentration [24, 30]. Assessment of ocular accommodation is simple and noninvasive and, hence, might be a reliable measure for blood sugar. To the best of our knowledge, this is the first study to assess the utility of ocular accommodation for predicting HbA1c in diabetes.

We found NPA significantly receded in diabetic subjects compared to the controls, indicating a loss in the ability to focus on closer objects. The average AoA in the diabetic group was 6.60D (i.e., 100/15.156 cm) compared to 10.55D (i.e., 100/9.478 cm) in controls. In a case-control study, Razavi et al. compared the mean NPA between diabetic subjects and age-matched healthy controls. They reported that the diabetic subjects had about twice the mean NPA reported in the controls (18.5 ± 4.4 cm vs. 9.5 ± 2 cm) [40]. In a recent case-control study by Abokyi et al. (2021, the mean AoA for diabetic subjects was significantly lower than that found in the nondiabetic subjects (10.1 ± 2.7D vs. 11.5 ± 2.4D, respectively). However, the mean AoA in their diabetes patients from Ghana was higher than that found in the current study (10.7 ± 1.52D compared to 6.6 ± 2.28D). Apart from the ethnic differences, the age profiles of the participants could play a role as the study participants recruited by Abokyi et al. were relatively younger (mean age 23.8 years) than those involved in our study (mean age 27.4 years). AoA is a function

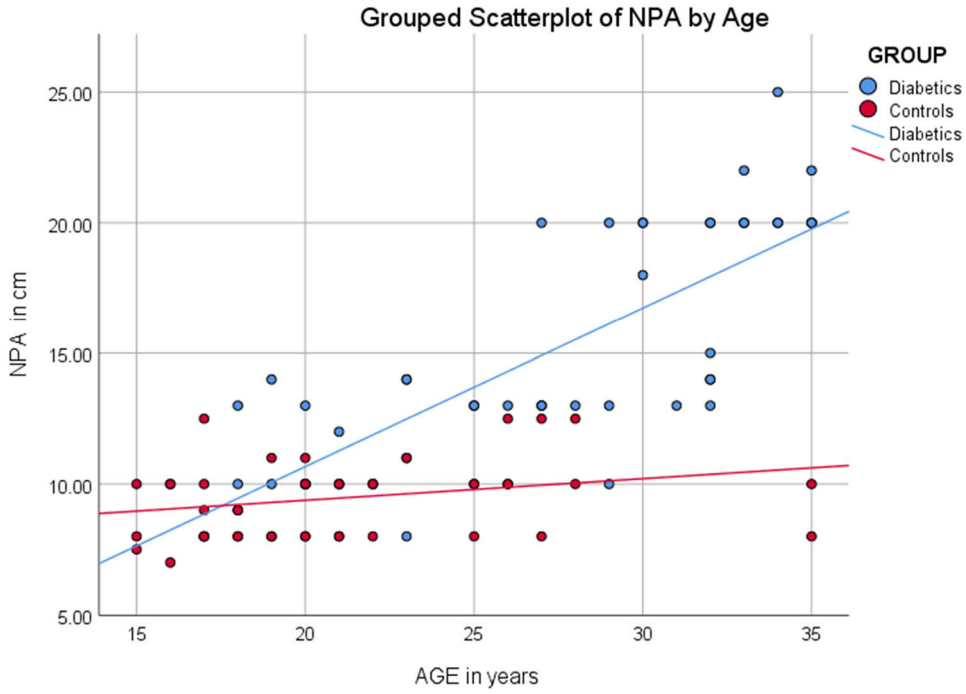

FIGURE 1 | Effect of diabetes on Near Point of Accommodation (NPA). NPA increases sharply with age in diabetics, while it increases steadily with age in healthy controls.

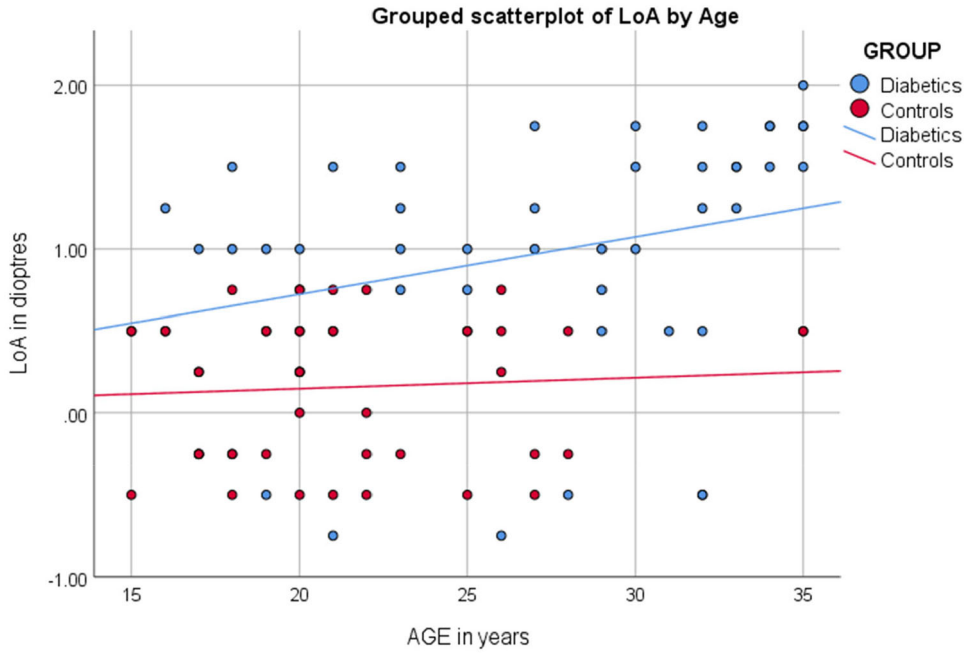

FIGURE 2 | Effect of diabetes on Lag of accommodation (LoA). Higher LoA is noted in patients with diabetes compared to controls. Additionally, LoA increases sharply with age in patients with diabetes, while a smooth increase is noted in controls.

of age; increasing age is associated with reducing AoA. Thus, younger participants will have higher AoA than adult subjects [26, 30].

Our study examined the association between HbA1c levels and accommodation functions, specifically NPA and LoA. Controlling for age and duration of diabetes, we observed a positive correlation between HbA1c and NPA ($r = 0.35$). This indicates that higher blood sugar levels are associated with receded NPA; conversely, lower blood sugar levels are linked to decreased NPA. However, no significant correlation was found between HbA1c and LoA, in contrast to a study by Nabovati et al. who found a significant moderate positive correlation between them [28]. The precise mechanism underlying the significant changes observed in accommodative function measures among individuals with diabetes is not fully understood. However, one

TABLE 2 | SEM results showing the contribution of eye accommodation in predicting HbA1c.

Model			Unstd. β	Std. β	S.E	C.R	*p* value
HbA1C	<---	Near point of accommodation	0.345	0.548	0.089	3.886	$p < 0.001$*
HbA1C	<---	Lag of accommodation	0.005	0.001	0.544	0.009	0.993
HbA1C	<---	Disease duration	0.665	0.275	0.341	1.952	0.051
HbA1C	<---	Participants' age	−0.167	−0.336	0.070	−2.383	0.017

Note: SEM = structural equation modeling; β = path coefficient.
*Significant, $p < 0.05$; $R^2 = 0.387$.

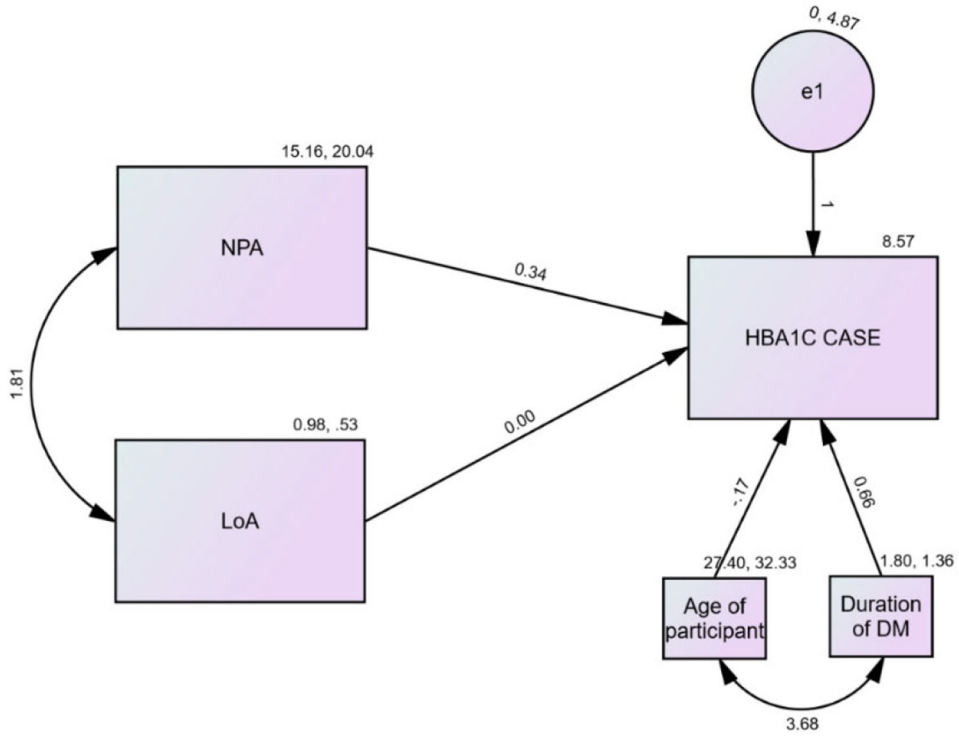

FIGURE 3 | Path model showing the relationship between HbA1c and predictor variables. Numbers on top of pointed arrows are path coefficients. Numbers on top of double-pointed arrows are covariance coefficients. Numbers on top of the variables in squares are the means, followed by the variance of the variables. ($R^2 = 0.387$).

TABLE 3 | Correlational analysis between HbA1c and accommodation parameters after adjusting for age and the duration of diabetes onset.

Control variables	Predictors	Correlation	df	*p* value
Age and diabetes duration	NPA	0.354	41	0.020*
	LoA	0.142	41	0.364

Abbreviations: LoA, lag of accommodation; NPA, near point of accommodation.
*$p < 0.05$.

hypothesis suggests that these "changes could be attributed to lenticular alterations resulting from the accumulation of sorbitol, a glucose derivative, within the lens fibers during episodes of hyperglycemia" [24]. Previous studies have demonstrated that biochemical changes, including alterations in enzyme activities, can lead to changes in lens elasticity and curvature [41]. Sorbitol accumulation creates a concentration gradient between the lens and aqueous humor, causing water (aqueous humor) to move into the lens through osmosis. This lens swelling reduces its elasticity, alters the refractive index, and impairs its ability to fully adjust when stimulated by the ciliary muscles [30, 41]. Additionally, reduced neural input to the ciliary muscles and a loss of ciliary muscle tone, commonly observed in diabetic patients, may contribute to these changes [28].

To answer the overarching question of whether ocular accommodation could predict HbA1c levels in diabetes, we ran a multiple regression analysis with HbA1c as a dependent variable against four predictor variables (age, onset of diabetes, AoA, and LoA). We found that NPA was the only significant predictor of HbA1c, and the model explained about 34.1% of the

changes in HbA1c. Additionally, SEM corroborated this finding and showed that NPA is a good predictor of blood sugar levels. The implication of this finding suggests that NPA might be influenced by HbA1c. When the NPA measured in a patient is markedly receded compared to the age-standard range, the recession may be attributed to changes in sugar level (HbA1c). We speculate that receded NPA in diabetes patients, which is not in tandem with their age-standard NPA, may be due to a significant change in their sugar levels. Therefore, a good predictor of HbA1c will be the NPA. We further suggest that NPA is a convenient yet cost-effective screening tool for diagnosing/screening and managing/monitoring blood sugar levels.

4.1 | Study Limitations

A significant limitation of our study is the subjective measurement of NPA by patient's self-reporting of the first sustained blur. While this method offers advantages such as speed and simplicity in a clinical setting [37], it has been observed to overestimate AoA and has high test-retest variability. Compared to other methods, the push-up-to-blur method gives higher values of AoA due to the effect of distance magnification [42]. It is recommended that future studies investigating AoA use other objective measures of AoA based on other techniques, such as the modified push-up-to-blur method and the minus-lens-to-blur method. Additionally, it is important to note that our study was conducted exclusively among diabetes patients who were relatively younger (under 40 years old). Therefore, caution should be exercised when attempting to generalize the findings to older individuals with diabetes, particularly those belonging to presbyopic age groups.

5 | Conclusion

The present study discovered a significant impairment in ocular accommodation among recently diagnosed type-1 diabetes patients compared to control subjects, demonstrating the accommodative system's high sensitivity to diabetes. Notably, a model using accommodative measures as predictors accounted for nearly one-third of the variance in HbA1c levels. We propose that an algorithm using variables from ocular accommodation assessments in diabetes patients could provide an economical method for evaluating HbA1c levels. LoA is not a good predictor of HbA1c.

Author Contributions

Bright Vandyke Okyere: conceptualization, methodology, data curation, supervision, formal analysis, investigation, writing – review and editing, writing – original draft, validation, and resources. **Benedict Ayobi:** methodology, software, data curation, supervision, formal analysis, investigation, validation, writing – review and editing, and visualization. **Hope Katumba:** conceptualization, investigation, writing – original draft, methodology, data curation, and formal analysis. **Samuel Abokyi:** conceptualization, software, methodology, data curation, supervision, formal analysis, validation, investigation, writing – review and editing, visualization, and project administration.

Acknowledgments

The authors have nothing to report.

Conflicts of Interest

The authors declare no conflicts of interest.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Transparency Statement

The corresponding author, Samuel Abokyi, affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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