# REFRACTIVE STATUS OF TYPE II DIABETES MELLITUS PATIENTS AT KENYATTA NATIONAL HOSPITAL



DR. CONSITY MWALE

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## DECLARATION

THIS DISSERTATION IS MY ORIGINAL WORK AND HAS NOT BEEN PRESENTED FOR A DEGREE IN ANY OTHER UNIVERSITY

Signed: Date: 13/07/06

**Dr. Consity Mwale**

## APPROVAL

**THIS DISSERTATION HAS BEEN SUBMITTED IN PART FUFILLMENT OF THE DEGREE OF MASTER OF MEDICINE (OPHTHALMOLOGY) WITH OUR APPRAVOL AS UNVERSITY SUPERVISORS:**

**DR. JEFITHA KARIMURIO**

MB.Ch.B. (Nrb), M.MED Ophthal. (Nrb), MSc-CEH (London).

LECTURER, DEPARTMENT OF OPHTHALMOLOGY, UON

Signed: _____

Date: 13/7/2006

**DR. MARGARET W. NJUGUNA**

MB.ChB. (Nrb), M.MED Ophthal. (Nrb), Paed. Ophthal. LVPEI (India).

LECTURER, DEPARTMENT OF OPHTHALMOLOGY, UON

Signed: _____

Date: 13.07.2006

## DEDICATION

WITH LOVE AND GRATITUDE TO MY FAMILY.

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## 2. LIST OF ABBREVIATIONS:

| | |
|---|---|
| BCVA | Best corrected visual acuity |
| CsME | Clinically significant macular edema |
| DM | Diabetes mellitus |
| DR | Diabetic retinopathy |
| DS | Diopter spheres |
| ECCE | Extracapsular cataract extraction |
| FBS | Fasting blood sugar |
| HBA1C | Glycosylated heamoglobin |
| HLA | Human leukocyte antigen |
| IDDM | Insulin dependant diabetes mellitus |
| IRMA | Intraretinal microvascular abnormalities |
| KNH | Kenyatta National Hospital |
| LE | Left eye |
| MOPC | Medical out patient clinic |
| NIDDM | Non insulin dependant diabetes mellitus |
| NPDR | Non proliferative diabetic retinopathy |
| NVD | New vessels at the disc |
| NVE | New vessels elsewhere |
| NVG | Neovascular glaucoma |
| NVI | New vessels in the iris |
| OHA | Oral hypoglycaemic agents |
| OR | Objective refraction |
| RE | Right eye |
| SLE | Slit lamp examination |
| SPSS | Statistical package of social sciences |
| TRD | Tractional retinal detachment |
| UON | University of Nairobi |

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## 4.0 ABSTRACT:

A hospital based cross sectional study of 96 type II diabetes mellitus patients attending the diabetic medical clinic at Kenyatta National Hospital.

**Aim:** To determine the prevalence and pattern of refractive errors among African type II diabetes mellitus patients and establish the relationship between baseline refractive status and degree of diabetic retinopathy and indicators of glycaemic control.

**Method:** The study was carried out in the month of November, 2005. The statistically predetermined sample size was 94 patients. The first 10 of the patients seen on each day of the diabetic medical clinic were included in the study. These patients were randomly booked at the diabetic medical clinic and had no prior knowledge of the study, hence no bias in case selection. The actual level of metabolic control was evaluated from measurement of HBA1C and FBS. The patients had full ocular examination including OR and SLE. Two eyes from 2 patients were excluded due to dense cataracts. After these eyes were excluded, data from both eyes were reported (190 eyes).

**Results:** The total number of subjects examined was 96. There were 58 females and 38 males. The mean age was 52 (range 28-76) years and the median was 53 years. The prevalence of myopia was 39.5% (75/190 eyes) and that of hypermetropia was 19.0% (36/190 eyes). To estimate the short term fluctuation in refraction caused by current level of metabolic control, the power of patients' own distant spectacles for 31(32.3%) patients and the measured refraction at presentation were correlated, statistically significant correlations were found (rho=0.945, p-value =0.001). Each patient was requested to come back for HBA1C results after 14 days, but only 84 (87.5%) patients came and these were reexamined to check for variations in refractive status.

There was a statistically significant correlation between refractive status at first presentation and day 14 (rho=0.978, p=0.001). This suggests that our prevalence estimates were unlikely to have been influenced by acute metabolic dysregulations. Of the 96 patients, 22.6% had DR and no patient was blind. Of the eyes with DR, 20.0% (15/75 eyes) were myopic, 19.4% (7/36 eyes) were hypermetropic and 26.6% (21/79 eyes) were emmetropic. There was no statistically significant correlation at first presentation, between refractive status and diabetic retinopathy (p=0.358), HBA1C (rho=0.130, p-value=0.249 among myopes) and FBS (rho=-0.089, p-value=0.438 among myopes and rho=0.158, p-value=0.350 among hyperopes). There was a statistically significant correlation between baseline refractive status and duration of DM (rho=0.260, p=0.001) and hypermetropic refractive status and HBA1C (rho=0.401, p-value=0.014) at first presentation.

**Conclusions:**

- The patients had poor glycaemic control i.e. 47.9% had HBA1C > 7.3% while 47.9% had FBS > 10.1 mmol/l.
- Refractive errors were seen in 58.5% of the patients, myopia was the commonest refractive error (39.5%) while 19.0% were hypermetropic.
- There was no statistically significant relationship between baseline refractive status and indicators of glycaemic control except for hypermetropic refractive status and HBA1C (rho=0.401, p-value=0.014).
- The number of DM patients having eye examination for the first time was less than in previous studies.

**Recommendations:**

- A study looking at the relationship between refractive status and DR should be conducted on patients with DR.
- According to the results of this study, it is not mandatory to ask for HBA1C or FBS results before issuing spectacle prescription to adult patients with type II diabetes mellitus. However, there is need to emphasize the need for good glycaemic control to minimize the other ocular complications. A similar study should be done on young people with type I diabetes mellitus.

## 5.0 LITERATURE REVIEW:

### 5.1 Introduction:

Diabetes is a disease in which the body does not produce, or cannot properly use insulin, an essential hormone needed to convert carbohydrates and other foods into the energy needed for daily life. After 20 years of diabetes without strict control of blood glucose levels, there is a 90 percent chance of developing eye disease. Ocular complications of diabetes include retinopathy, vitreous hemorrhage, cataract, glaucoma and changes in refraction. Signs and symptoms include: frequent urination, abnormal thirst, excessive appetite accompanied by weight loss, fatigue, recurrent vaginal yeast infections and visual changes. People with type I (insulin-dependent) diabetes, which generally occurs under age 30, must take insulin injections daily. Type II (usually non-insulin-dependent) diabetes is 10 times more common and usually occurs in people over 40, particularly those who are overweight and inactive. [1,41]

The cornerstone of treatment is diet modification. If diet alone fails to normalize blood glucose (sugar) levels, patients take a prescribed oral medication that stimulates insulin secretion or improves the body's ability to use insulin. Some people with type II diabetes use a combination of insulin and oral medication. [1] People with diabetes should never neglect visual symptoms because they might be due to complications of the disease. Some symptoms may be corrected with standard prescription lenses, while others may need medication or surgery. The most common diabetes-related eye symptoms are: changes in refraction, variable vision or focus and blurred or hazy vision.

There is insufficient information on the magnitude and pattern of refractive errors among Africans with type II diabetes mellitus. While refractive errors among diabetics may be regarded a minor public health research priority because spectacles may readily correct it. [2] However, the health cost imposed by refractive correction on the community can be very high especially among diabetics who in our setting have to buy their own medications (oral hypoglyceamic agents and insulin).

## 5.2 Definitions:

Emmetropia is the refractive state in which parallel rays of light from a distant object are brought to a focus on the retina and in this study being a refractive status of -0.50 to +0.50 diopter spheres or spherical equivalent.

Myopia is a refractive state in which an object at infinity converge too soon and thus focus in front of the retina and in this study being a refractive error less than – 0.5 diopter spheres or spherical equivalent. Simple myopia was myopia greater than -6.00 diopter spheres or spherical equivalent.

Hypermetropia is a refractive state in which an object at infinity focuses behind the retina and in this study being a refractive error greater than +0.5 diopter spheres or spherical equivalent.

New patients were DM patients having their first eye examination for DR while lost to follow up was failure to turn up for review at the DM eye clinic 6 months from the last scheduled appointment.

Diabetic retinopathy is a progressive microangiopathy affecting the precapillary arterioles, capillaries and venules of the retina. Glycosylated haemoglobin (HBA1C) measurement is the most widely used measure of long term glycaemic control in diabetes. Glycosylated haemoglobin is produced by the non-enzymatic glycosylation of haemoglobin at a rate proportional to the prevailing glucose concentration. The level of HBA1C depends upon red cell lifespan and prevailing blood glucose concentration. Provided red cell lifespan is normal, HBA1C measures mean blood glucose concentration over the preceding 60-90 days. [3]

## 5.3 Prevalence of refractive errors among DM patients:

In the study by Sultanov et al, a total of 220 diabetics (428 eyes) aged 16 to 79, 144 females and 76 males, where examined to define the incidence rate and the clinical manifestations of diabetic involvement of the retina found that the prevalence of myopia was 20.6%, hypermetropia was 33.1% and emmetropia was 46.3%. [4] Fledelius et al, considered refractively adult patients referred for general eye examination from other (non-ophthalmic) departments (n = 1416; 2832 eyes) and found that thirty per cent of all eyes had negative refractive values. The highest myopia prevalence, about 40%, was seen in the age group 26-45 years. The diabetics (representing 762 eyes) showed a shift towards negative refractive values (37.9% with myopia) as compared to non-diabetics (27.5%). The diabetic surplus was due to low degree myopia cases. The association between myopia and (well-controlled) diabetes seemed to be a new observation. [5]

## 5.4 Refractive errors in the general population:

The magnitude of refractive errors is not reliably known and there is a large variation in global prevalence of refractive errors. However the impact of refractive errors including myopia and visual impairment on individuals and the community at large is not trivial. [2]A population-based survey that was conducted in the Shihpai district of Taipei, Taiwan, found that the prevalence of myopia, astigmatism, and anisometropia significantly increased with age (all $P < 0.01$). It also found that there was no significant difference in refractive errors between people with and without diabetes mellitus. [7]The Barbados Eye Study, a population-based study, included 4709 black Barbados-born citizens, or 84.0% of a random sample, 40 to 84 years of age. The prevalence of myopia was 21.9% and was higher in men (25.0%) than in women (19.5%). The prevalence of hyperopia was 46.9% and was higher in women (51.8%) than in men (40.5%). The prevalence of myopia decreased from 17% in persons 40 to 49 years of age to 11% in those 50 to 59 years of age, but increased after 60 years of age. The prevalence of myopia (hyperopia) increased (decreased) after 60 years of age, which is inconsistent with data from other studies. [8]

Beaver Dam Eye Study reported that the prevalence of myopia declined from 42.9% in those 43 to 54 years of age to 14.4% in those 75 years of age or older. [40] The Baltimore Eye Survey found a similar trend across gender and ethnic groups. The prevalence of myopia in black men and white women, for example, decreased from 34.0% and 42.1%, respectively, at age 40 to 49 years to 10.5% and 12.9%, respectively, at age 80 years or more. [20] The Framingham Offspring Eye Study reported that the prevalence of myopia declined from 52% in those 35 to 44 years of age to 20% in those 65 to 74 years of age.

One explanation for this decline was that the prevalence of myopia increased during the middle decades of the 20th century. Those born in earlier decades have not been as heavily exposed to putative myopigenic factors such as near work and therefore have a lower prevalence compared with younger, more myopic generations with greater near work demands. An alternate explanation is that the prevalence of myopia has not changed appreciably over time, but is lower in older adults because it declines with age as a physiological change. [9, 36]

A hospital based study of refractive status among Kenyan Africans referred to the eye clinic for refraction, done at Kenyatta National Hospital in 1986 found a prevalence of 43% for simple myopia and 2.6% for high myopia. Epidemiology studies on myopia have identified possible association with family history, education, intelligence and near work. [10, 11] A study on ocular refraction in Zaire showed that the frequency of spherical refractive errors in Zairian black patients was 56%: (simple myopia: 33% myopia over 5 D: 1%, hypermetropia: 22%), astigmatism was seen in 44% (myopic astigmatism: 31% and hypermetropic astigmatism: 11%). The data of Zairians were similar to those of non-Zairian black patients. [12]

## 5.5 Blood glucose level versus refractive error:

Transient refractive changes are a well recognized feature of DM and ophthalmologists should always check for DM in any case of rapidly changing refraction. [13, 14] Diabetes mellitus may affect refraction with short-term fluctuations and more permanent alterations. [15]

The generally accepted view is that short-term fluctuations alter the refraction of the lens, primarily by alterations in osmotic pressure caused by changes in the blood glucose level and accumulation of sorbitol and fructose in the lens by the sorbitol pathway. No general agreement has been reached regarding the direction of these refractive changes. [16] It has been suggested that there is a higher degree of myopia when there is a high blood glucose level and a hyperopic shift when the blood glucose level normalizes. [13] Other studies, however, suggest alterations in a hyperopic direction at high blood glucose levels, as confirmed in animal studies. [17,18,19]

Studies have done to evaluate the clinical course and the characteristics of transient refractive error occurring during intensive glycaemic control of severe hyperglycaemia and showed that a transient hyperopic change occurred in all patients receiving improved control after hyperglycaemia. Statistically significant positive correlations were found between refractive changes and magnitude of blood glucose and HBA1C (p-value=<0.001). [26,27,28] With regard to the more permanent alterations in refraction with duration of diabetes there are fewer studies. Some authors have found an increased prevalence of low degree myopia among diabetic compared with non-diabetic patients. [5,21] Jain et al found no difference in prevalence of myopia in diabetic versus non-diabetic subjects, although diabetic patients with higher myopia were less likely to develop retinopathy. [22] Refractive changes associated with diabetes mellitus which are due to changes in blood sugar levels, are both acute and chronic. Regarding chronic refractive changes in diabetic patients, Duke-Elder reported that hyperglycaemia led to the development of myopia, while hypoglycaemia led to the development of hyperopia. [14]

Duration of DM has earlier been shown to have a clear influence on lens thickness as was confirmed in a twin study. [6,23,24] Whether the increased lens thickness is responsible for the observed higher prevalence of low degree myopia among diabetics remains unclear, especially as the refractive index of the lens is altered at the same time. Since lens thickness increases with age, separating the effect of duration of diabetes from that of increasing age is difficult. [25] For generations it has been taught that myopic change is the principal response to hyperglycaemia in diabetes mellitus. Recently, however, a hyperopic concept has been advanced, to suggest that a change towards hypermetropia has possibly become the more frequent finding in diabetics with unstable refraction. In a study by Fledeliuc HC et al, it was not possible to point out an association with specific patterns of metabolic dysregulation. There results were further discussed in relation to previous refraction studies demonstrating increased myopia prevalence in diabetics in general, as compared to non-diabetics. Apparently this cannot be explained merely by a possibly overlooked transient refractive change under periods of poor metabolic control. [18]

## 5.6 Influence of refractive status on diabetic retinopathy:

Diabetic retinopathy is the commonest cause of moderate to severe retinal blindness. It is a complex multifactorial disease. Approximately 8% of legally blind individuals are reported to have diabetes and approximately 12% of new blindness is due to diabetic retinopathy. Insulin dependant diabetic patients with retinopathy are 29 times more likely to become blind than nondiabetic individuals. [29] In India the estimated incidence of diabetic retinopathy in tertiary care diabetes center is an estimated 34.1%. [39]

The urban population prevalence of diabetic retinopathy in the population based Andhral Pradesh Eye Disease Study (APEDS) was 7.8%. [22] The diabetic retinal disease typically progresses through a succession of recognizable stages from early nonproliferative to advanced proliferative retinopathy. [11,30,31,32]

In a study of fundus findings in black Africans with newly diagnosed type II diabetes mellitus, the prevalence of diabetic retinopathy was 30.4% and of these 8.2% had vision-threatening retinopathy. In other hospital based studies, the prevalence of diabetic retinopathy were 18.3% and 49.8% respectively in a rural and urban Kenyan population. [33,34,35] In a study of the characteristics of the course of diabetic retinopathy, there were 88 eyes with myopia, 142 with hypermetropia, and 198 with emmetropia. Diabetic changes of the retina were detected in 40.9% of myopic refraction cases, in 65.2% of emmetropia and in 70.4% of hypermetropia cases. The severity of the involvement was lesser in myopia than in other types of refraction. In medium-severity myopia no proliferative stages of diabetic retinopathy were observed, and in high myopia (10 eyes) no diabetic involvements of the fundus oculi were revealed. In anisometropia diabetic symptoms on the myopic side were either absent or poorly manifest. These findings point to the role of refractive status in the pathogenesis of diabetic involvement of the retina and their progress. [4]

In the study by Hovener G et al, two groups of patients with diabetic retinopathy were tested by refraction. Patients with advanced retinopathy and those with early diabetic retinopathy had about the same proportion of refractive errors as the normal population.

The only important difference was seen in middle and high myopic eyes, which occurred less frequently when diabetic retinopathy was present. [37] Some of the risk factors which influence the incidence rate of ocular complications in diabetic patients are well known, as are duration of diabetes mellitus, blood sugar level, blood pressure, ocular pressure and eye perfusion. On the other hand, it is also known that amblyopia, optic atrophy, low blood pressure in central retinal artery and retinitis pigmentosa are ocular conditions which are not associated with proliferative diabetic retinopathy. It was also noticed that complications of diabetes in high myopic eyes are less prominent than in emmetropic eyes. [38]

## 6.0 RATIONALE:

There is insufficient information on the prevalence and pattern of refractive errors among Africans with type II diabetes mellitus. Refractive errors among diabetics may be regarded a minor public health research priority because spectacles may readily correct it. However, the health cost imposed by refractive correction on the community can be very high especially among diabetics who in our setting have to buy their own medications. Moreover, the refraction of a diabetic patient is not straight forward as one has to consider the glycaemic control before issuing a spectacle prescription. This is a big challenge when we consider our patients as the majority tend to be poorly controlled.

In Africa and in this region to be more specific, there is no literature if any regarding the pattern of refractive errors in type II diabetes mellitus patients. The study will provide baseline data necessary for future reference in the study area as most such studies have been done in whites. The study will also give an insight on the correlations of FBS/HBA1C and baseline refractive status. This may be helpful when issuing spectacle prescriptions for diabetics. It is interesting that the progression of diabetic retinopathy has been found to be affected by the refractive error and this study may show the relationship between degree of diabetic retinal disease and baseline refractive status among black African type II diabetics.

## 7.0 RESEARCH HYPOTHESIS:

Myopia, a common finding in diabetic patients, is affected by glycaemic control and could be protective against diabetic retinopathy.

## 8.0 STUDY OBJECTIVES:

### 8.1 Broad objective:

To determine the prevalence and pattern of refractive errors among African type II diabetes mellitus patients at Kenyatta National Hospital.

### 8.2 Specific objectives:

1. To determine the prevalence and pattern of refractive errors among African type II diabetes mellitus patients.
2. To establish the relationship between refractive status and diabetic retinopathy.
3. To correlate baseline refractive status to glycaemic control,
    a. Fasting blood sugar.
    b. Glycosylated haemoglobin.

## 9.0 RESEARCH METHODOLOGY:

### 9.1 Study design:

A cross-sectional hospital based study.

### 9.2 Study variables:

The variables that were used to achieve the stated objectives are as follows:

- Independent variables e.g age / type II DM / FBS / HBA1C / duration of diabetes / type of diabetes treatment / past ocular surgery / glycaemic control.
- Dependent variables included patient's refractive status and grade of diabetic retinopathy.

### 9.3 Study population:

Diabetes mellitus patients attending the diabetic medical clinic at Kenyatta National Hospital.

### 9.4 Study period:

Data collection was in the month of November, 2005.

### 9.5 Sample size:

N=minimum sample size required

Z=1.96, to give 95% probability of not exceeding D

D=0.1, the minimum tolerable random sampling error

P=43%, assumed population prevalence

$N = Z^2 P (1-P)/D2$

Thus $N = 1.96^2(0.43) (1-0.43)/0.1^2 = 94$

Therefore minimum number of subjects required is 94

## 9.6 Sampling method:

The first 10 of the patients seen at the diabetic medical clinic were included in the study. These patients were randomly booked at the diabetic medical clinic and had no prior knowledge of the study, hence, no bias in case selection. The principle investigator could not be able to conduct full ocular examination on more than 10 patients in a day.

## 9.7 Inclusion criteria:

Patients with type II diabetes mellitus attending the diabetic medical clinic who were willing to be investigated (FBS and HBA1C).

## 9.8 Exclusion criteria:

Eyes with ocular conditions that could interfere with accurate refraction, such as corneal opacity or visually impairing opaque media, were excluded.

## 9.9 Data handling:

Analysis of data collected was done with the help of a statistician using statistical package for social sciences (SPSS). Where appropriate, statistical comparison was done.

## 9.10 Study instruments and materials:

- A questionnaire (appendix a)
- Snellen chart, illiterate E chart and near vision chart
- Mydriatic drops e.g. Tropicamide 1% eye drops
- 20D Volk loupe and 90D Volk loupe
- Heine indirect ophthalmoscope
- Slit lamp (Haag Streit 900)
- Heine Retinoscope

- Refraction trial set
- Autorefractor
- Laboratory tests: Fasting blood sugar at and glycosylated haemoglobin at MOPC.

## 11 Procedure:

formed consent was obtained from each participant after explaining the aim and cedures to be involved in this study. A questionnaire was used to collect information patient demographic characteristics, duration and treatment of diabetes mellitus. The gnosis of diabetes was based on internationally accepted clinical criteria. Onset of betes was defined as the month and year when the first treatment was given. The actual vel of metabolic control was evaluated from measurement of glycosylated haemoglobin nd fasting blood glucose performed approximately 3 hours before the ophthalmic examination. The selected patients were taken to the eye clinic after they were reviewed at he diabetic medical clinic, for full ocular examination including objective refraction and lit lamp examination under mydriasis.

The basic ophthalmological examination included assessment of visual acuity and intraocular pressure, slit lamp microscopic examination, funduscopy after mydriasis with 0.5% tropicamide, 0.5% phenylephrine hydrochloride, and 1% cyclopentolate hydrochloride. Diabetic retinopathy was graded according to WHO criteria (as shown in the questionnaire), which involved slit lump biomicroscopy. Visual acuities without correction and with best correction were recorded.

The spectacle correction was recorded for patients who wore spectacles at presentation. Refraction was done objectively by retinoscopy and later refined subjectively. The power of lens giving the best corrected visual acuity after refinement was recorded for both near and distant vision. Refractive status was graded using the WHO criteria. In the eyes with astigmatism, spherical equivalent values were used as the refractive values. The spherical equivalent of refraction was calculated as spherical value plus half of the negative cylinder value. To check for fluctuations in refractive status, patients were reexamined 14 days after first presentation as they came for their HBA1C results. Further treatment was recommended where necessary. Only drugs registered in Kenya were used.

## 9.12 Minimization of errors and biases:

The questionnaire was pre-tested and appropriate adjustments made to ensure achievement of the study objectives. Other colleagues in the eye department were familiarized with the study objectives and on how to administer the questionnaires. The questionnaire was administered individually and in private to avoid influences from third parties and eliminate prestige bias. Repeat questioning was employed to ensure truthfulness of the responses. Patients were seen by the consultants in the eye clinic to reconfirm the results and this cross checking by several examiners minimized examiner variables. Field editing of the data was carried out whenever possible. Data verification was done at data entry stage with the help of the statistician.

## 9.13 Ethical considerations:

Informed consent was collected from each participant after explaining the aim of the study and all procedures that were involved. Further treatment was recommended where necessary and only drugs registered in Kenya were used (appendix b). The participants were assured of full and free access to their results (FBS and HBA1C).

## 9.14 Study limitations:

Costs of laboratory investigations.

## 10.0 RESULTS:

**Table I: Distribution of study population by age and sex (N=96 patients):**

| *Distribution by Age* | *Frequency, n (%)* |
|---|---|
| • 28 – 37 | 10(10.4) |
| • 38 – 47 | 22(22.9) |
| • 48 – 57 | 30(31.3) |
| • 58 – 67 | 26(27.1) |
| • 68 – 77 | 8(8.3) |
| ***Total*** | ***96 patients (100)*** |
| ***Distribution by Sex*** | |
| • Male | 38(39.6) |
| • Female | 58(60.4) |
| ***Total*** | ***96 patients (100)*** |

The majority of patients (81.3%) examined were in the age range 38 – 67 years. The mean, minimum and maximum being 52 years, 28 years and 76 years respectively and the range was 48 years. The median was 53 (SD 11.4) years. The mean age among the male patients was 53 years while that of the female patients was 51 years. There was no statistically significant difference in the mean age of male and female subjects (P – value =0.296). Majority of the patients were females (60.4%). The male: female ratio was 1:1.5.

**Figure I: Distribution of study population by age and sex (N=96):**

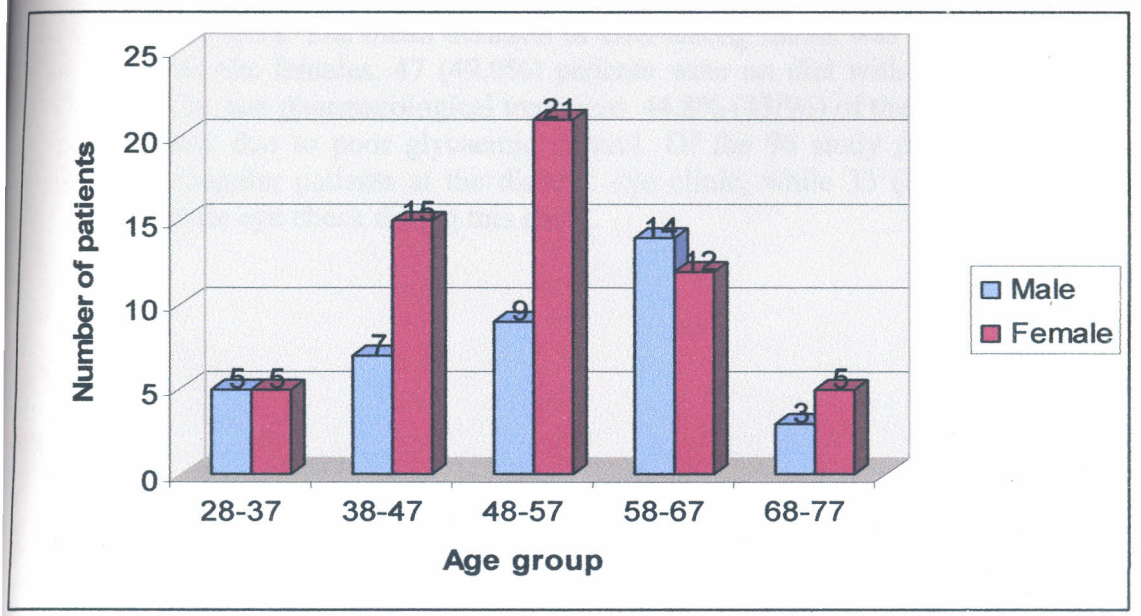


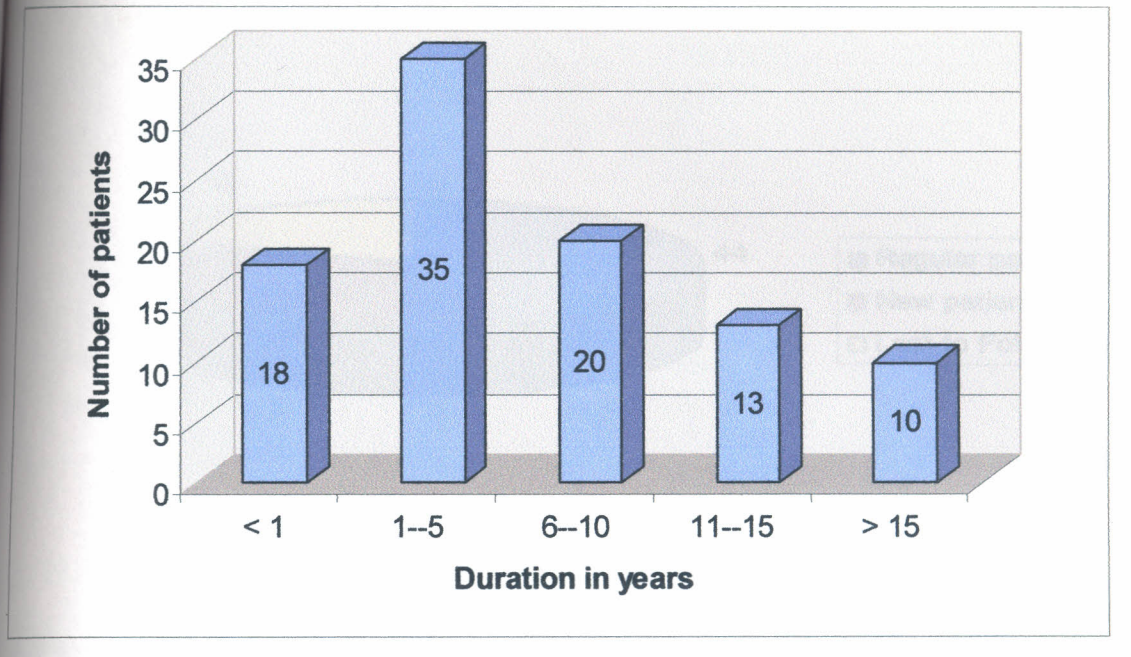

Figure I above shows that the majority of patients (81.3%) examined were in the age range 38 – 67 years.

**Table II: Clinical characteristics of DM (N=96 patients):**

| *Duration of Diabetes mellitus in years* | *Frequency, n (%)* |
|---|---|
| • Less than 1 | 18(18.8) |
| • 1 – 5 | 35(36.5) |
| • 6 – 10 | 20(20.8) |
| • 11 – 15 | 13(13.5) |
| • > 15 | 10(10.4) |
| ***Total*** | ***96 patients (100)*** |
| *Mode of treatment* | |
| • Diet only | 6(6.2) |
| • Diet & OHA | 47(49.0) |
| • Diet, OHA & Insulin | 24(25.0) |
| • Diet & Insulin | 19(19.8) |
| ***Total*** | ***96 patients (100)*** |
| *Attendance of the DM Eye Clinic* | |
| • Regular Patients | 44(45.8) |
| • New Patients | 33(34.4) |
| • Patients Lost to Follow – up | 19(19.8) |
| ***Total*** | ***96 patients (100)*** |

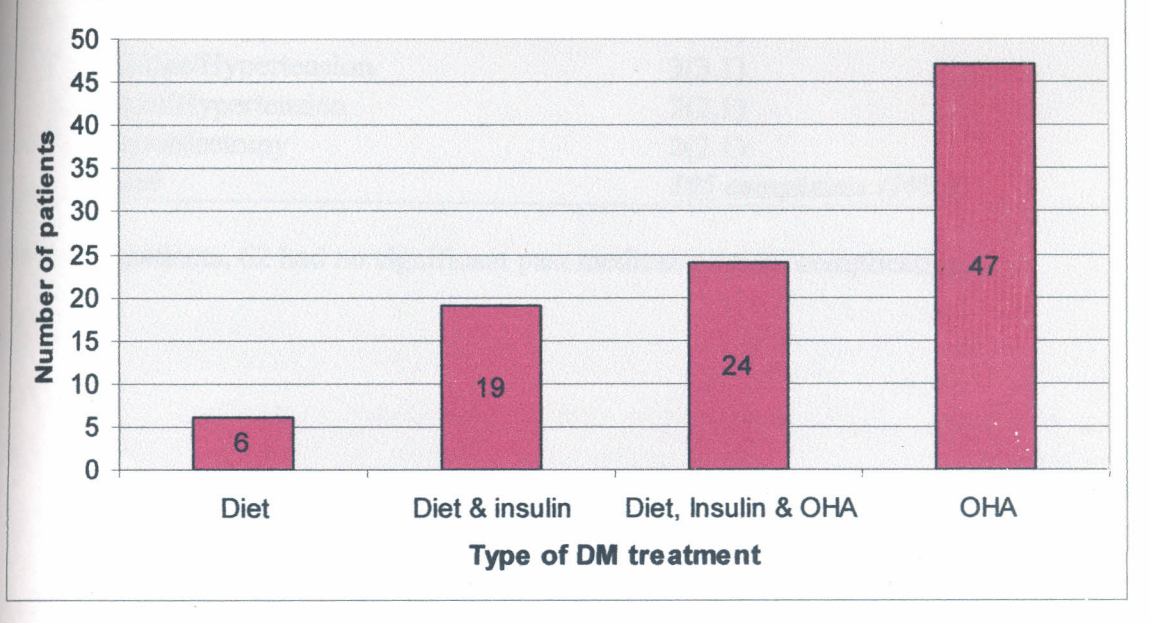
Most of the patients (76.1%) had diabetes mellitus for less than 11 years. The minimum, maximum, mean and standard deviation for the duration of DM, were 0.1 years, 30.0 years, 6.9 years and 6.6 years respectively. There was no statistically significant difference in duration of DM between male and female subjects (p=0.137). There was a statistically significant correlation between refractive status and duration of DM (rho=0.260, p=0.001). The mean duration of DM among males was found to be 8 years and 6 years for the females. 47 (49.0%) patients were on diet with OHA while only 6 patients were on non pharmacological treatment. 44.8% (43/96) of the patients were using insulin probably due to poor glycaemic control. Of the 96 study patients, 44 (45.8%) patients were regular patients at the diabetic eye clinic, while 33 (34.4%) patients had their first diabetic eye check during this study.

**Figure II: Duration of diabetes mellitus in years (N=96 patients):**



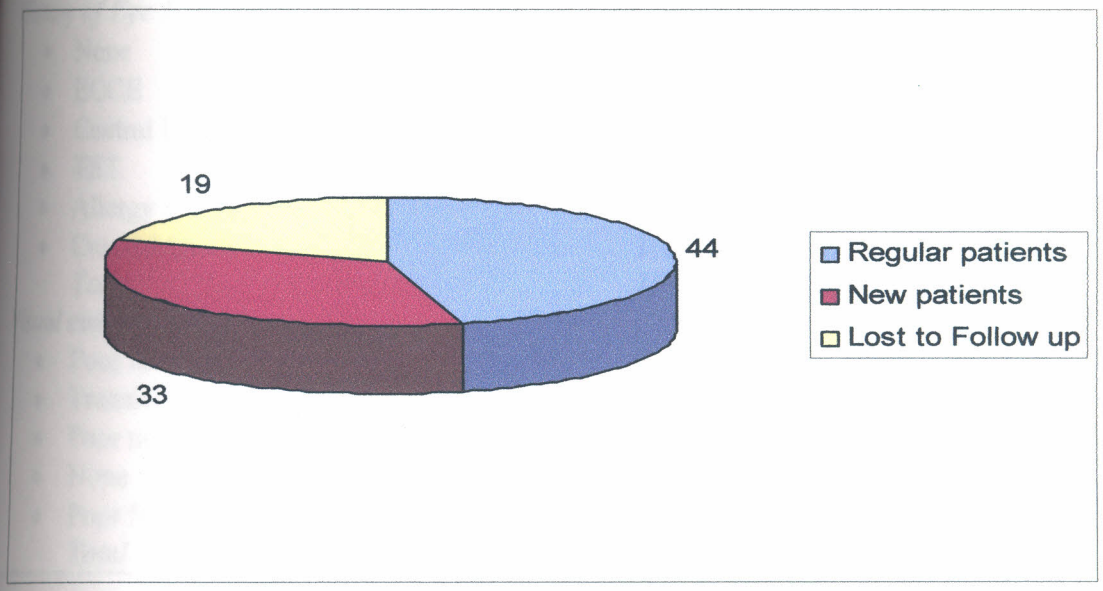

Majority of the patients (76.1%) had had DM for a period of < 11 years and only 10 patients had DM for more than fifteen years.

**Figure III: Mode of diabetes mellitus treatment (N=96 patients):**




Only 6.2 % of the patients were on non pharmacological treatment.

**Figure IV: Attendance of the diabetic eye clinic (N=96 patients):**




The majority of the patients (45.8%) were on follow-up at the diabetic eye clinic.

**Table III: Previous medical/surgical history (N=96 patients):**

| *Previous Medical/Surgical History* | *Frequency, n (%)* |
|---|---|
| • None | 62(64.6) |
| • Hypertension | 32(33.3) |
| • DM Foot/Hypertension | 4(4.2) |
| • Cardiac/Hypertension | 3(3.1) |
| • Renal/Hypertension | 2(2.1) |
| • Thyroidectomy | 2(2.1) |
| ***Total*** | ***105 complaints (109.4)*** |

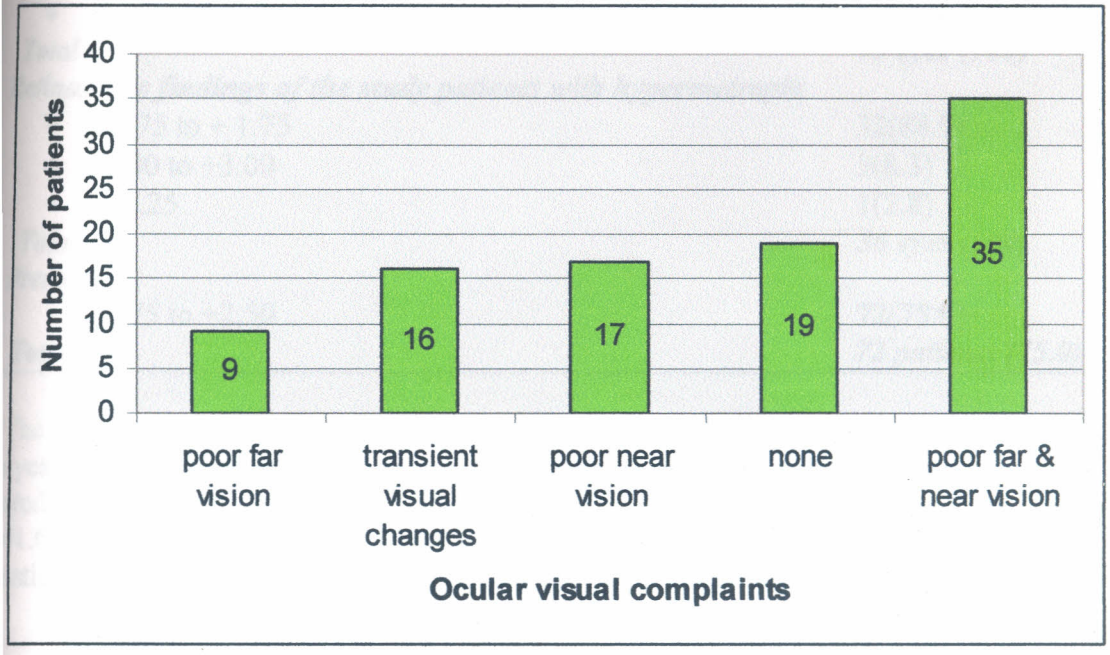
Of the 96 patients, 62 had no significant past medical/surgical complications.

**Table 1V: History of eye disease, treatment and visual complaints:**

| *History of Eye Disease* | *Frequency, n (%)* |
|---|---|
| • None | 170(89.5) |
| • ECCE | 11(5.8) |
| • Central Laser | 2(1.1) |
| • TET | 2(1.1) |
| • Allergy | 4(2.1) |
| • Corneal Graft | 1(0.5) |
| ***Total*** | ***190 eyes (100.0)*** |
| *Visual complaints* | |
| • Poor far vision | 9(9.4) |
| • Transient visual loss | 16(16.7) |
| • Poor near vision | 17(17.7) |
| • None | 19(19.8) |
| • Poor far and near vision | 35(36.5) |
| ***Total*** | ***96 complaints (100.0%)*** |

Of the 96 patients (190 eyes) examined, 11 patients had uniocular ECCE, 2 patients had uniocular central laser, 1 patient had a uniocular corneal graft and 19 patients did not have any visual complaints.

**Figure V: Distribution of visual complaints (N=96 patients):**



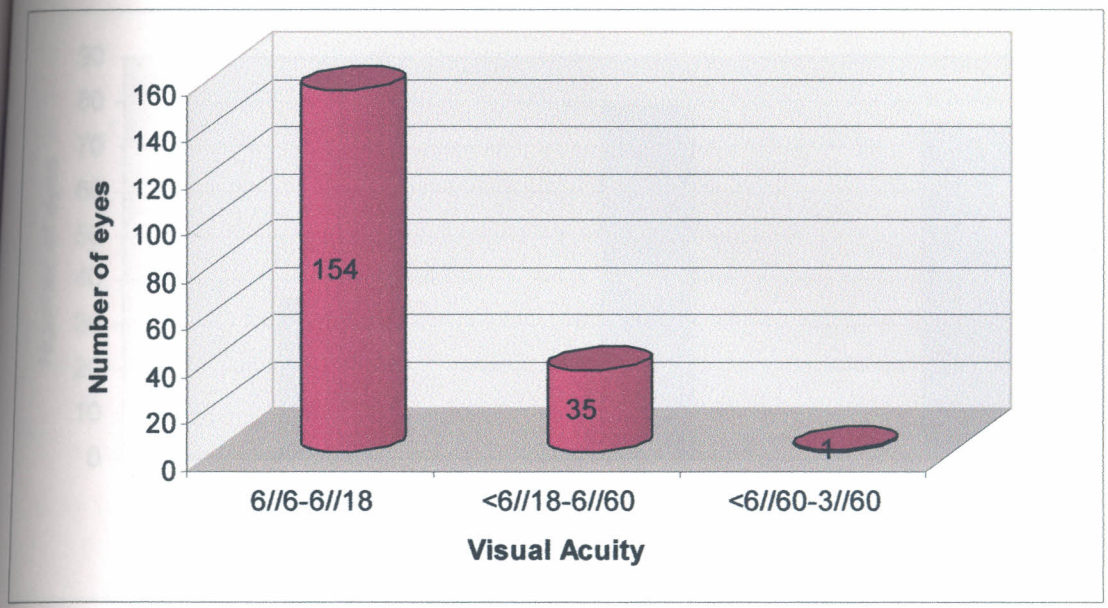

Only 16.7% of the patient complained of transient visual changes.

**Table V: Eye examination findings:**

| *Monocular visual acuity without spectacle correction* | *Frequency, n (%)* |
|---|---|
| • 6/6 | 31(16.3) |
| • 6/9 | 32(16.8) |
| • 6/12 | 44(23.2) |
| • 6/18 | 47(24.7) |
| • 6/24 | 13(6.8) |
| • 6/36 | 11(5.8) |
| • 6/60 | 11(5.8) |
| • <6/60-3/60 | 1(0.5) |
| *Total* | ***190 eyes (100)*** |
| ***Monocular BCVA*** | |
| • 6/6 | 139(73.2) |
| • 6/9 | 30(15.8) |
| • 6/12 | 15(7.9) |
| • 6/18 | 3(1.6) |
| • 6/24 | - |
| • 6/36 | - |
| • 6/60 | 2(1.1) |
| • <6/60-3/60 | 1(0.5) |
| *Total* | ***190 eyes (100)*** |
| ***Retinoscopy findings of the study patients with myopia*** | |
| • - 0.75 to – 1.75 | 58(77.3) |
| • - 2.00 to -3.00 | 10(13.3) |
| • <-3.25 | 7(9.3) |
| *Total* | ***75 eyes (100)*** |
| ***Retinoscopy findings of the study patients with hypermetropia*** | |
| • + 0.75 to + 1.75 | 32(88.9) |
| • +2.00 to +3.00 | 3(8.3) |
| • >+3.25 | 1(2.8) |
| *Total* | ***36 eyes (100)*** |
| ***Presbyopes*** | |
| +0.75 to +2.50 | 72(75.0) |
| *Total* | ***72 patients (75.0)*** |

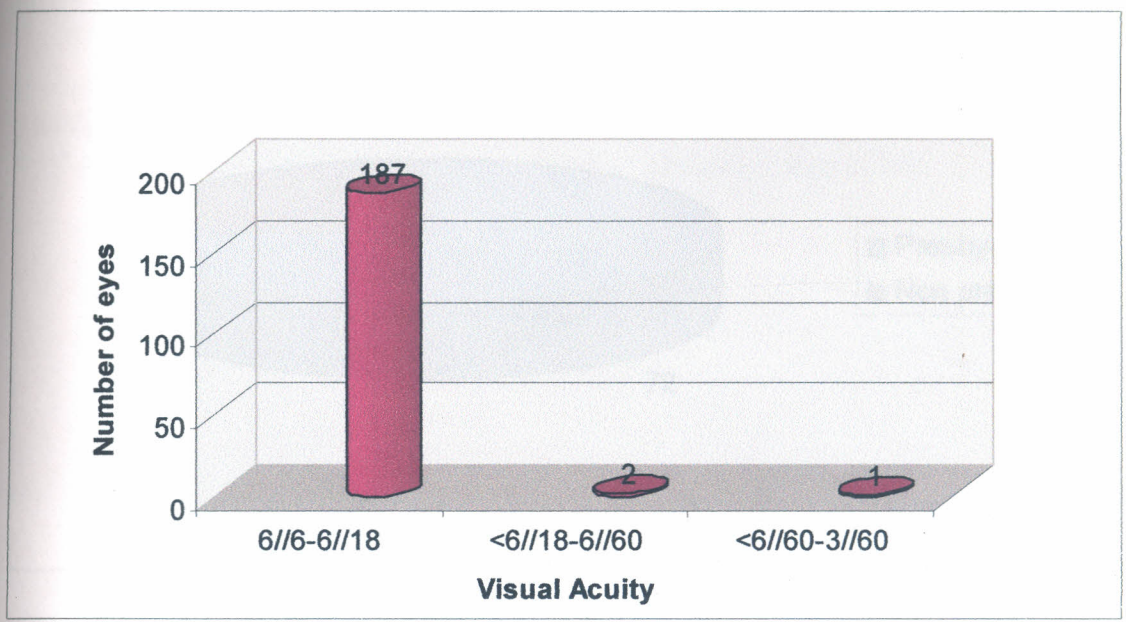
The monocular visual acuity without correction was better than or equal to 6/18 in 154 eyes (81.0%). One eye with a vision of less than 6/60 - 3/60 had optic atrophy. Of the 190 studied eyes, 39.5% were myopic (75 eyes), 19.0% were hypermetropic (36 eyes) and 41.6% were emmetropic (79 eyes). 72 patients were presbyopic. Thirteen eyes with astigmatism all had a myopic spherical equivalent of -3.00 DS to -0.75 DS.

**Figure VI: Monocular visual acuity without spectacle correction (N=190 eyes):**



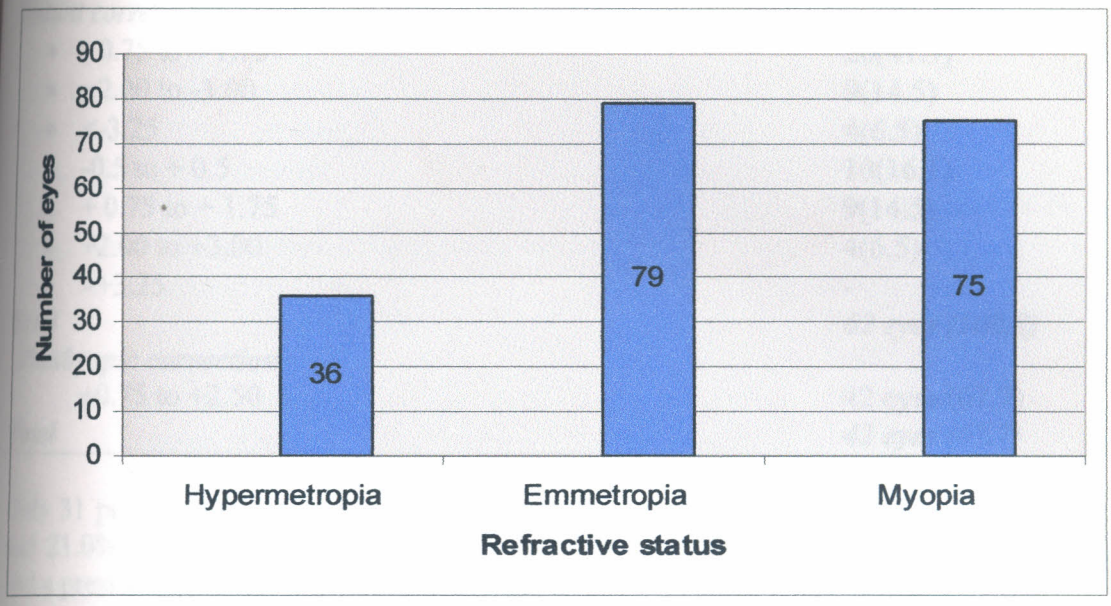

One eye with a vision of <6/60-3/60, had optic atrophy.

**Figure VII: Best corrected monocular visual acuity (N=190 eyes):**



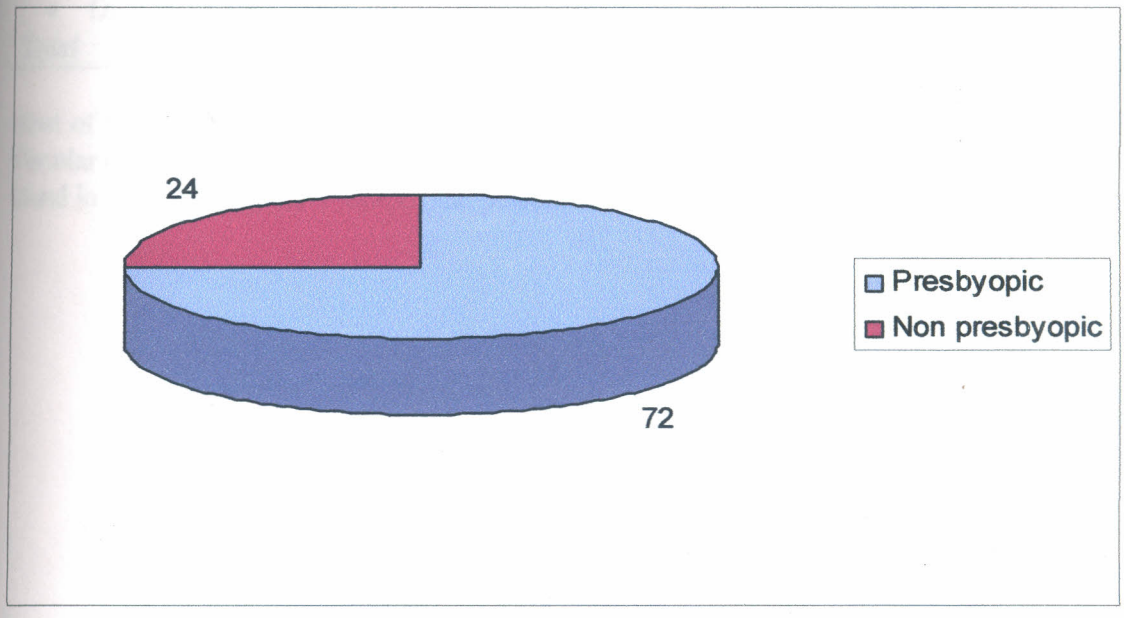

Majority of the 190 eyes (98.4 %) had normal monocular BCVA (of 6/6-6/18).

**Figure VIII: Refractive status (N=190 eyes):**




The majority patients (41.6%) were emmetropic and while 39.5% were myopic.

**Figure IX: Presbyopic status (N=96 patients):**




Only 25.0% of the patients were not presbyopic.

**Table VI: Power of spectacle correction (N=62 eyes):**

| *Distant correction* | *Frequency, n (%)* |
|---|---|
| • - 0.75 to – 1.75 | 26(41.9) |
| • - 2.00 to -3.00 | 9(14.5) |
| • <-3.25 | 4(6.5) |
| • -0.5 to + 0.5 | 10(16.1) |
| • + 0.75 to + 1.75 | 9(14.5) |
| • +2.00 to +3.00 | 4(6.5) |
| • >+3.25 | - |
| *Total* | ***62 eyes (100.0)*** |
| ***Presbyopic correction*** | |
| +0.75 to +2.50 | 42 eyes (67.7) |
| *Total* | ***42 eyes (67.7)*** |

Only 31 patients had spectacles at presentation, of these, 62.9% wore myopic corrections and 21.0% wore hypermetropic corrections. Twenty one (67.7%) of these patients also had a presbyopic correction at presentation.

**Table VII: Fundus Examination Findings (N=190 eyes):**

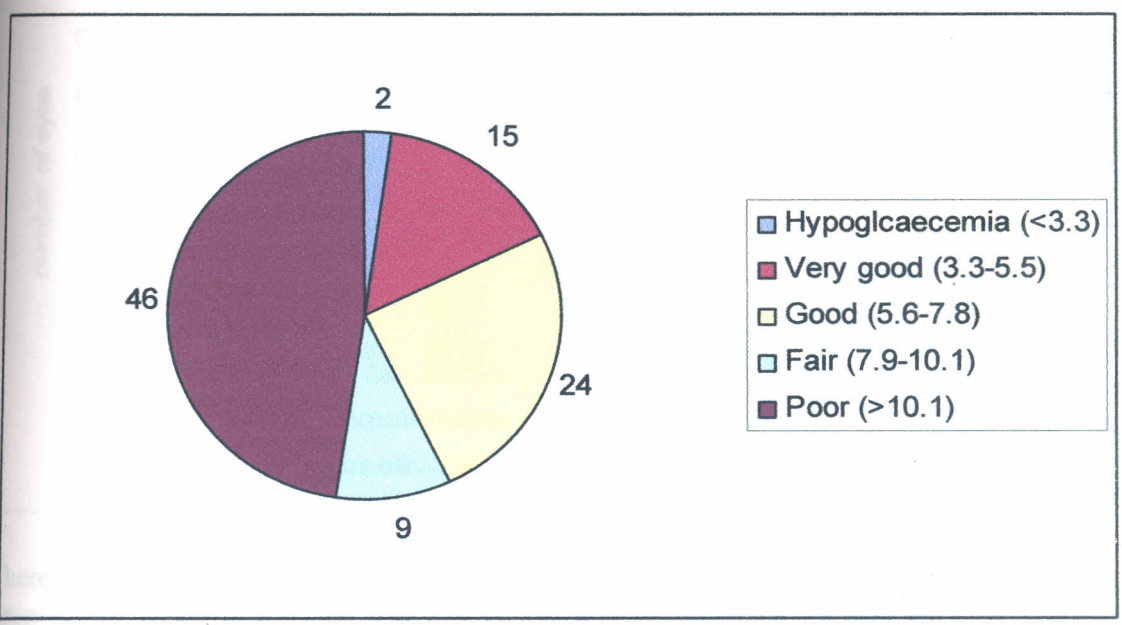
| ***Distribution of DM retinopathy by grading*** | ***Frequency, n (%)*** |
|---|---|
| • Normal | 147(77.4) |
| • Diabetic Retinopathy | 43(22.6) |
| *Total* | ***190 eyes (100.0)*** |

Most of the patients (77.4%) had normal fundus findings while 22.6% had mild NPDR. Macular oedema and retinal detachment which might affect the refractive status were not found in any of the eyes. None of the patients had advanced stage of DR.

| Table VIII: Laboratory findings (N=96 patients): | |
|---|---|
| ***Distribution of fasting blood sugar levels in mmol/l*** | ***Frequency, n (%)*** |
| • <3.3 (hypoglycaemia) | 2(2.1) |
| • 3.3 – 5.5 (very good control) | 15(15.6) |
| • 5.6 – 7.8 (good control) | 24(25.0) |
| • 7.9 – 10.1 (fair control) | 9(9.4) |
| • >10.1 (poor control) | 46(47.9) |
| *Total* | ***96 patients (100.0)*** |
| ***Distribution of Glycosylated haemoglobin levels (%)*** | |
| • <2.9 (hypoglycaemia) | 3(3.1) |
| • 2.9 – 4.2 (excellent control) | 13(13.5) |
| • 4.3 – 7.3 (good control) | 34(35.4) |
| • 7.4 – 11.4 (fair control) | 30(31.3) |
| • >11.4 (poor control) | 16(16.7) |
| *Total* | ***96 patients (100.0)*** |

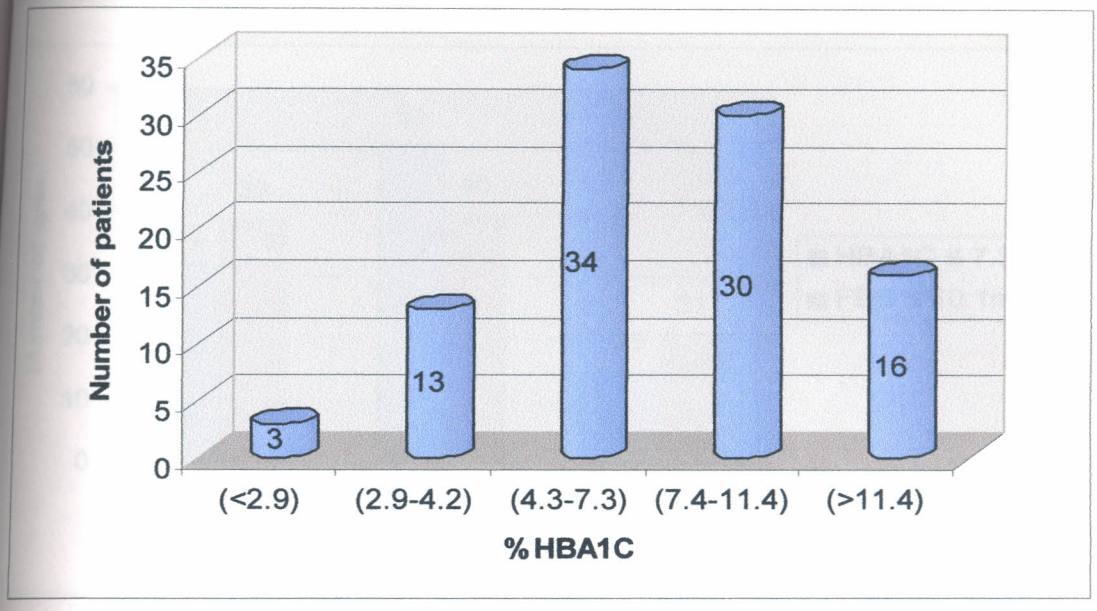
Only 52.1% (50/96) patients of the 96 were well controlled as per FBS. The minimum, maximum, mean and standard deviation for the FBS, were 3.0 mmol/l, 26.4 mmol/l, 10.4 and 4.8 mmol/l respectively. Only 50 (52.1%) of the 96 study patients were well controlled as per glycosylated haemoglobin levels. The minimum, maximum, mean and standard deviation for HBA1C, were 2.2%, 19.4%, 8.3% and 3.8% respectively. Cross tabulations of HBA1C and FBS at first presentation was statistically significant (r=0.188 and p=0.045).

**Figure X: Distribution of fasting blood sugar levels in mmol/l (N=96 patients):**



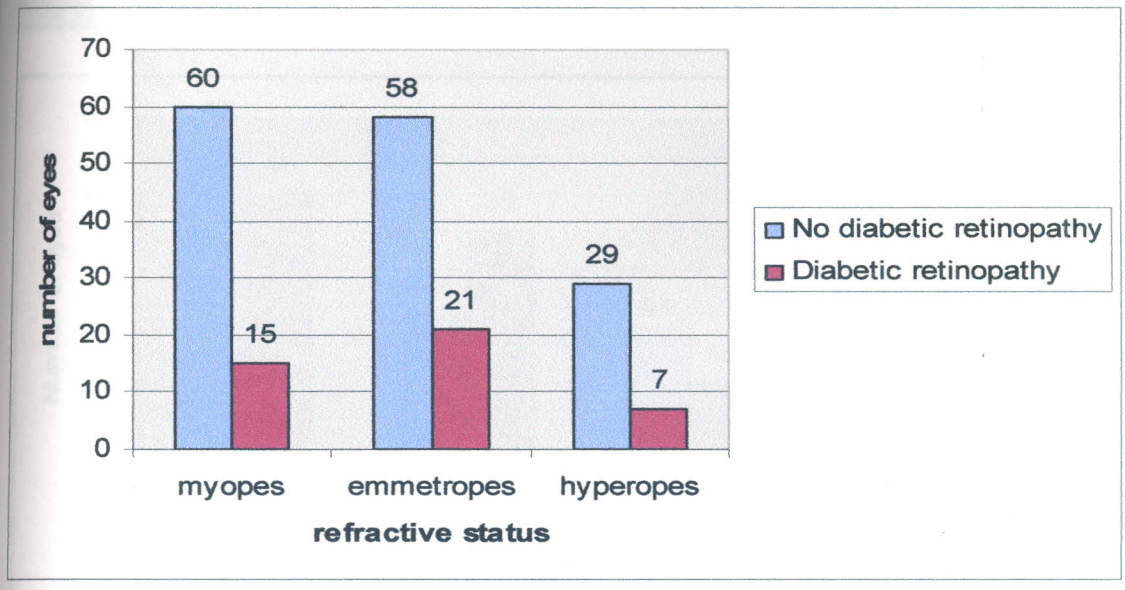

Only 52.1% (50/96) of the 96 patients were well controlled as per FBS (FBS ≤10.1 mmol/l).

**Figure XI: Distribution of glycosylated haemoglobin (%) (N=96 patients):**



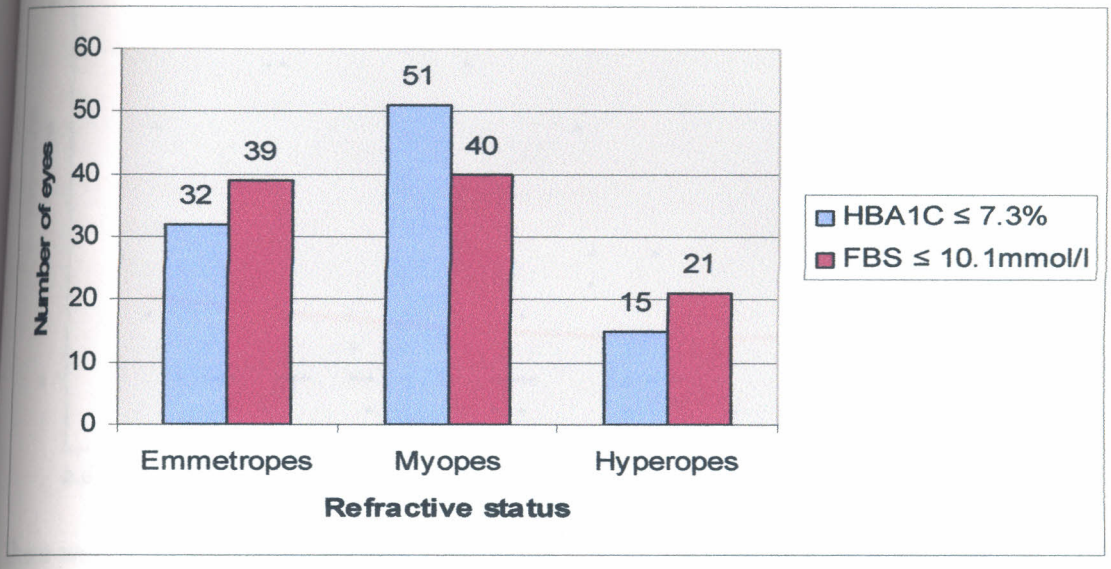

Only 52.1% (50/96) of the 96 study patients were well controlled as per HBA1C (HBA1C% ≤ 7.3.

**Figure XII: Distribution of refractive status and DR (N=190 eyes):**



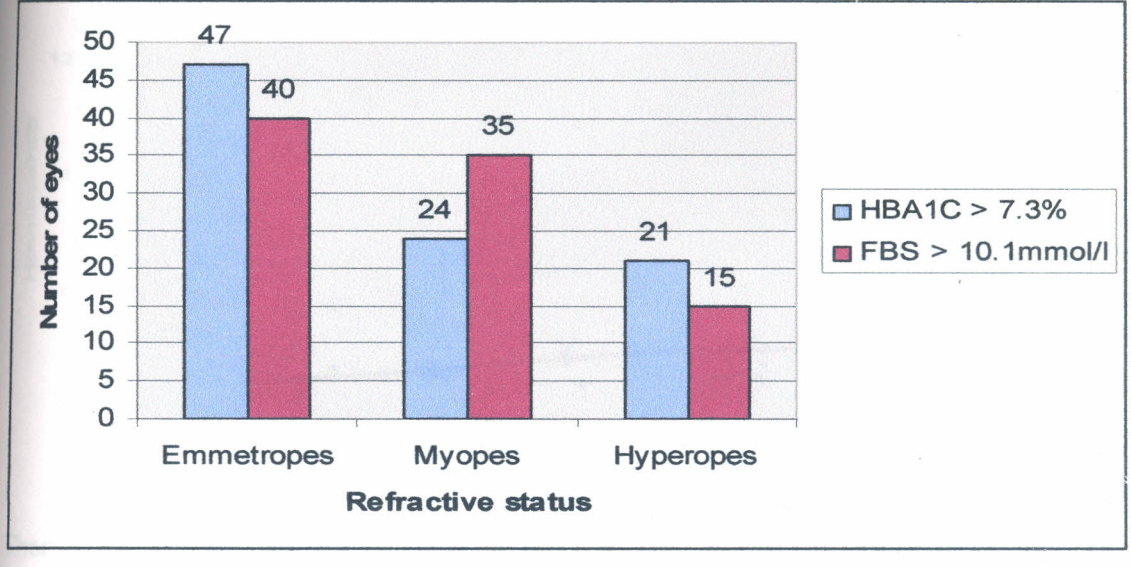

There was no statistically significant correlation between refractive status and diabetic retinopathy (p=0.358).

**Figure XIII: Refractive status with good glycaemic status (N=100 eyes for FBS, N=98 eyes for HBA1C):**



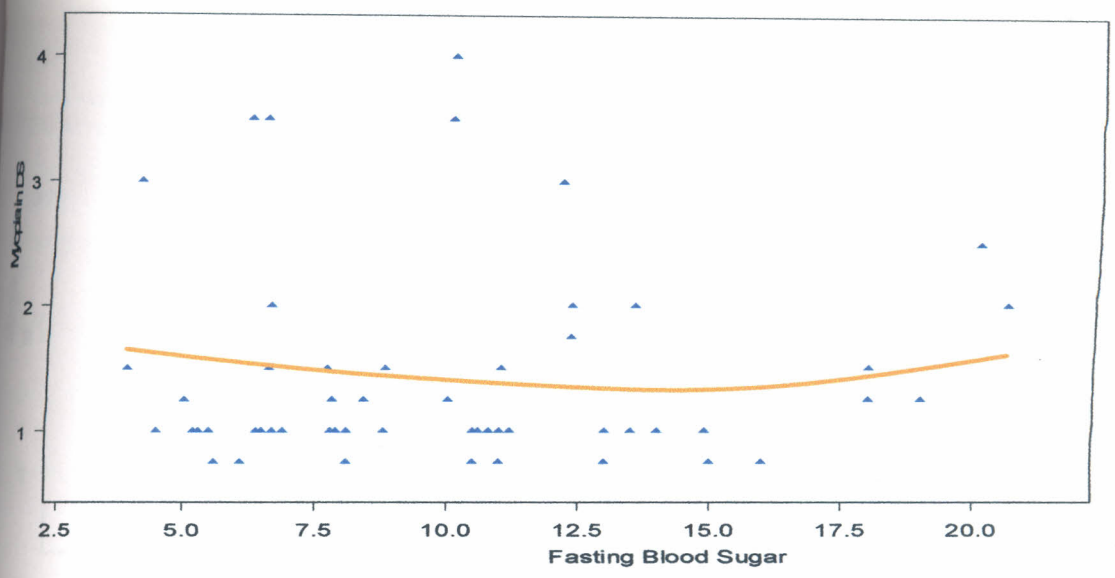

Analysis of the pattern of baseline refractive errors among patients with good control of HBA1C/FBS on the first day of the study, showed that myopes were 52.0% of the patients with HBA1C $\leq$ 7.3% and 40.0% of the patients with FBS $\leq$ 10.1 mmol/l.

**Figure XIV: Refractive status versus poor glycaemic status (N=90 eyes for FBS, N=92 eyes for HBA1C):**



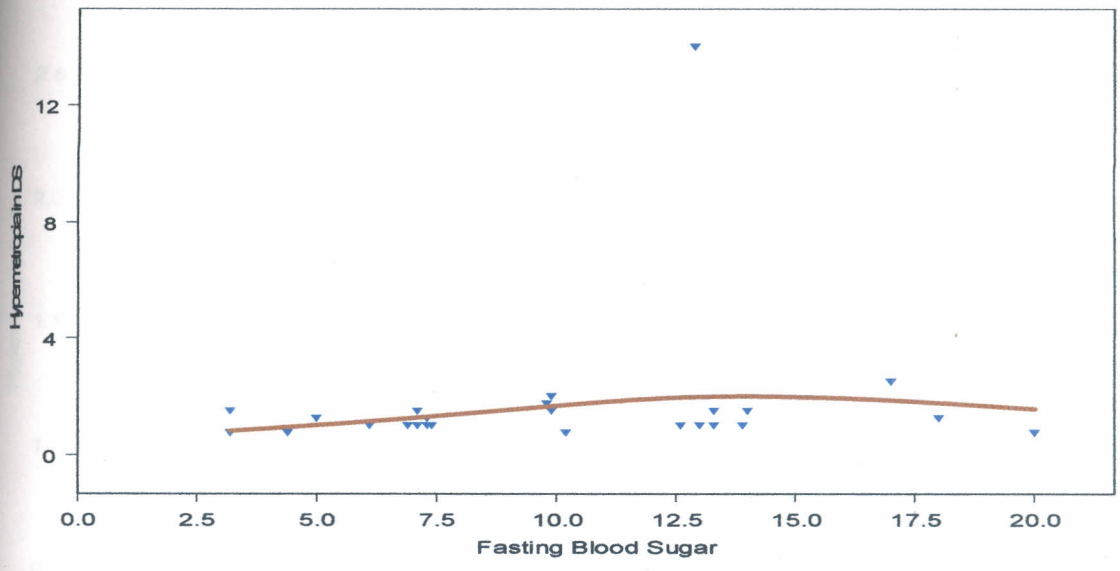

Analysis of the pattern of baseline refractive errors among patients with poor control of HBA1C/FBS on the first day of the study showed that myopes were 26.1% for patients with HBA1C > 7.3% and 38.9% for patients with FBS > 10.1 mmol/l.

**Figure XVa: Relationship between myopia and FBS in mmol/l (N=75 eyes):**



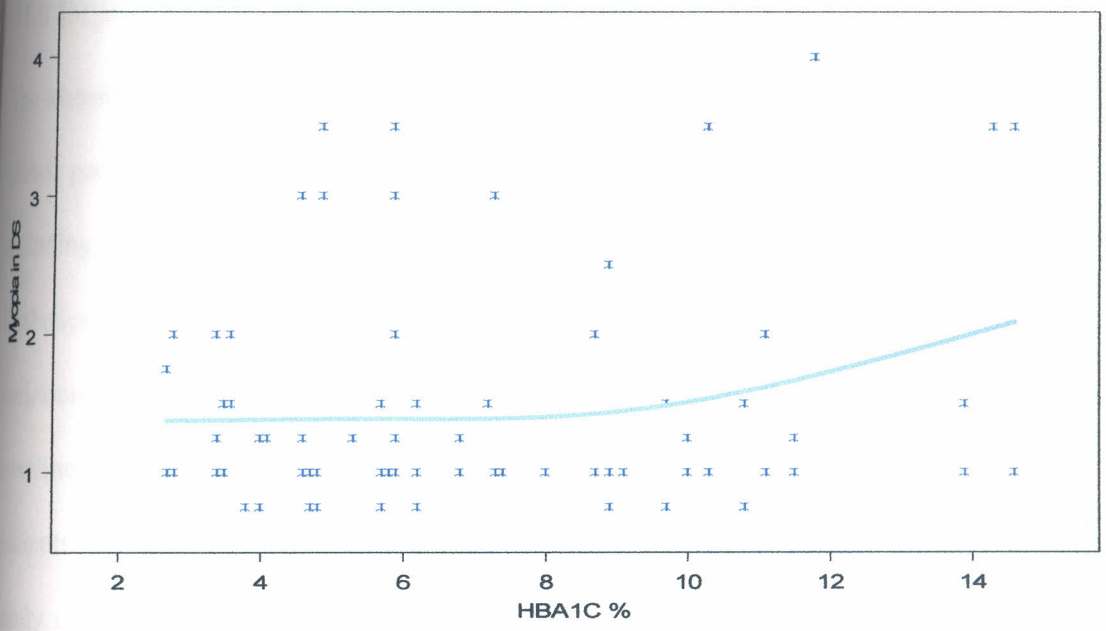

There was no correlation between myopic refractive status and FBS concentration on the first day of the study (rho = -0.087, P-value = 0.438). Overall, there was a slight myopic shift as the degree of hyperglycaemia reduced or increased from 12.5 mmol/l. This means that the degree of hyperglycaemia may not have affected the myopic refractive status of the patients.

**Figure XVb: Relationship between hypermetropia and FBS in mmol/l (N=36 eyes):**



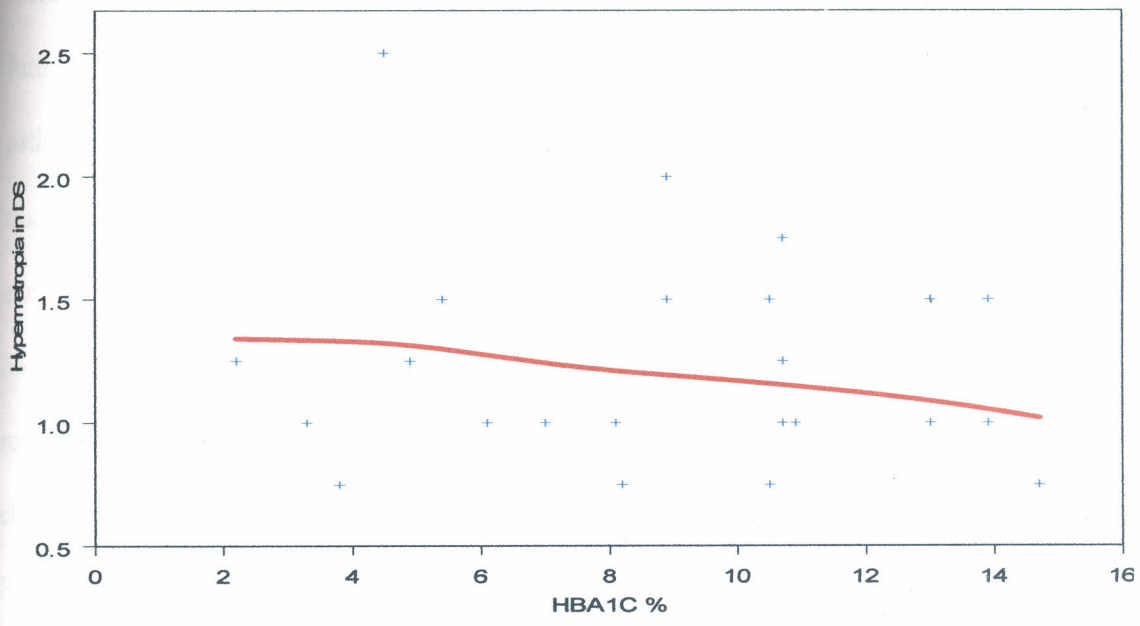

There was a slight myopic shift as the FBS result increased or reduced from 12.5%. There was no statistically significant correlation between hypermetropia and FBS (rho = 0.158, p-value = 0.350). This means that the degree of hyperglycaemia may not have affected the hypermetropic refractive status.

**Figure XVIa: Relationship between myopia and HBA1C % (N=75 eyes):**




As depicted above, the patients were likely to become more myopic as the degree of hyperglycaemia by HBA1C% result increased beyond 8.0%. Overall, there was no statistically significant correlation between myopia and HBA1C results (Rho = 0.130, p-value = 0.249).

**Figure XVIb: Relationship between hypermetropia and HBA1C % (N=36):**




There was a statistically significant correlation between hypermetropia and HBA1C results (rho = 0.401, p – value = 0.014). There was a myopic shift as HBA1C% increased.

## 11.0 DISCUSSION:

The magnitude of refractive errors is not reliably known and there is a large variation in global prevalence of refractive errors. However, the visual impact of refractive errors including myopia on individuals and the community at large is of public health concern. [2] Diabetics form a special group as they tend to have changing refractive errors due to variations in blood sugar levels. [7,26,27] To our knowledge, this study provides the first baseline data on the prevalence and pattern of refractive errors in African type II DM patients who are on DM treatment and attending the diabetic medical clinic. The present study also provides an opportunity to compare the prevalence of myopia among type II DM patients and other refractive errors with the general populations.

The statistically predetermined sample size was 94 patients. However, 96 patients were included in the study. More patients could not be recruited to increase the sample size further due to high costs of laboratory investigations. Of the 96 type II diabetes mellitus patients who were included in the study, 38 were males and 58 were females. The overall study participation rate was 100.0% (96/96). Two eyes from two different patients were excluded due to hazy media (dense cataracts). After these eyes were excluded, data from both eyes were reported (190 eyes). Each patient was requested to come back for HBA1C results 14 days later, but only 84 (87.5%) patients came and these were reexamined to check for variations in refractive status. HBA1C was done once at first presentation while FBS was repeated at second presentation for the 84 patients (167 eyes, one excluded due to dense cataract) who came for review.

The study population mean age was 52 years with a population standard deviation of 11.4 years. This is because our patients were type II DM patients which is common in people older than 30 years. [1] The majority of patients (81.3%) examined were in the age range 38-67 years. The mean age among the male patients was 53 years while that of the female patients was 51 years. There was no statistically significant difference in the mean age of male and female subjects (P – value =0.296) **(figure I)**. In a similar study done by Sultanov et al, a total of 220 diabetics (428 eyes), with an age range of 16 to 79 years were seen. The sex distribution showed more females (65%) compared to males (35%) which compares with what was found in this study. [4]

Duration of DM has been shown to have a clear influence on lens thickness as has been confirmed in a twin study. [23,24] Whether the increased lens thickness is responsible for the observed higher prevalence of low degree myopia among diabetics, as was the case in this study, remains unclear, especially as the refractive index of the lens is altered at the same time. In this study, the majority of patients (76.1%) had suffered from DM for less than 11 years. The mean duration of DM among males was found to be 8 years and 6 years for the females with a mean difference of 2 and a p – value of 0.137 **(figure II)** which was not statistically significant. Fledelius et al has reported thicker lenses and increasing myopia with increasing duration of DM, which was statistically significant. [23] A similar trend was found with a myopic shift as the duration of DM increased ($p<0.001$). However we did not assess thickness of lenses in this study.

Regarding treatment of DM we found that 44.8% (43/96) of the subjects were using insulin alone or in combination with OHA while 49.0% (47/96) did not use any insulin at all. It appears that most of the patients were on insulin alone or combined with OHA in order to improve glycaemic control as all the study patients were type II DM patients. There was no statistically significant correlation between refractive status and mode of DM treatment (p=0.061), but there was a statistically significant correlation between mode of DM treatment and HBA1C% (p=0.029) **(figure III)**.

Diabetic retinopathy is the commonest cause of moderate to severe retinal blindness. Approximately 8.0% of legally blind individuals are reported to have diabetes and approximately 12.0% of new blindness is due to diabetic retinopathy. [30] The vast majority of blindness due to DR is preventable and this yields direct economic and tangible benefits. As there is a DM epidemic underway worldwide and Africa has not being spared, the University of Nairobi decided to build a data bank on DM and the eye by conducting studies between 1997 and 2001. [34,35] One of these studies by Kariuki et al showed that 49.8% had DR while 82% were having an eye examination for the first time. [34] In this study, 45.8% (44/96) were old DM patients on follow up at the diabetic eye clinic while 19.8% (19/96) were old diabetics who had been lost to follow up. The patients who were having there first DM eye check were 34.4% (33/96). This shows an improvement in the number of new patients having their first DM eye examination **(figure IV)**.

Complications of DM at presentation were studied and were as follows: 62 patients had no significant past medical or surgical complications, 32 patients were hypertensive, 4 patients had both diabetic foot and hypertension **(table III)**. Subjective complaints of the patients who were included in the study were analyzed: 89.5% (170/190 eyes) of the patients had no significant history of eye disease, 19 (19.8%) patients had no visual symptoms, 16 (16.7%) had transient visual changes and 5.8% (11/190 eyes) had ECCE **(table IV).** Previous studies show a high prevalence of eye diseases such as cataracts, glaucoma and retinopathy among diabetic patients. [33,34,35] In this study, the majority of patients had good vision and no complications of DM or significant past history of eye disease. This low prevalence of ocular and systemic complications of DM among the study subjects may explain why there were no patients with advanced DR or blinding retinal disease in this study.

Monocular visual acuity without spectacle correction of the 190 eyes from the 96 study patients was as follows: 154 eyes (81.1%) had a vision of 6/6 to 6/18, 35 eyes (18.4%) had a vision of less than 6/18 to 6/60 and 1 eye with optic atrophy had a vision of less than 6/60 to 3/60 **(figure VI)**. Monocular best corrected visual acuity of the 190 eyes was as follows: 187 eyes (98.4%) had normal vision of 6/6 to 6/18, 2 eyes had a vision of less than 6/18 to 6/60 and 1 eye with optic atrophy had a vision of less than 6/60 to 3/60 **(figure VII)**. Refractive status of the 190 eyes at presentation was as follows: 79 eyes (41.6%) were emmetropic, 75 eyes (39.5%) were myopic and 36 eyes (19.0%) were hypermetropic **(figure VIII)**. The majority of the 96 patients (75.0%) were presbyopic **(figure IX)**.

In a study by Sultanov et al, there were 88 eyes (20.6%) with myopia, 142 (33.2%) with hypermetropia, and 198 (46.2%) with emmetropia showing a higher prevalence of hypermetropia among his diabetic subjects. [4] This was not the case in this study. The prevalence of myopia in this study (39.5%) is almost the same as that found by Boayue et al in 1986 at KNH who found a similar prevalence of 43.0% in the Kenyan African general population referred to the eye clinic for refraction which compares well with this study. [10] Therefore, the prevalence of myopia among DM patients at the MOPC may not be different from that of the general Kenyan population attending the eye clinic at KNH. In a study done by Kaimbo Wa Kaimbo et al in 1996, the frequency of spherical refractive errors in Zairian black patients was 56.0%: (myopia: 34.0% and hypermetropia: 22.0%). [12] Ching-Yu Cheng et al found no significant difference in refractive error between people with and without diabetes mellitus. [7]

Cross tabulations of the refractive status and diabetic retinopathy were reviewed in 190 eyes. Diabetic changes were observed in 20.0% of myopic refractive cases, 19.4% in hypermetropic cases and 26.6% in emmetropic cases. However there was no statistical significance (p=0.358) **(figure XII)**. The prevalence of DR in this study was 22.6% **(table VII)**. The optic disc and retinal neovascularization are less prominent and less frequent in myopic eyes in patients suffering from diabetes mellitus. The exact mechanisms of this phenomenon are not well known, but there is some evidence that there is a reduced blood flow in myopic eyes which is associated with less damaged microcirculation in eyes of patients with diabetes mellitus. [22,36,37,38] It was not possible to comment on such a finding in this study as all myopic patients had simple myopia with 20.0% (15/75 myopic eyes) having mild NPDR.

Thus in the present study we have not been able to investigate the possible relationship between severity of diabetic retinopathy and refractive error.

The Sultanov et al study observed diabetic changes in the retina in 40.9% of myopic eyes, 65.2% of emmetropic cases and 70.4% of hypermetropic cases. The severity of involvement was less in myopia than in other types of refraction. In medium severe myopia, no proliferative diabetic retinopathy was observed, and in high myopia (10 eyes) no diabetic involvement of the fundus oculi was found. In anisometropia diabetic symptoms on the myopic side were either absent or poorly manifested. [4] Therefore, this study does not compare well with the study by Sultanov et al which had similar conclusions to the studies by Dujic et al, Jain et al and Hovener et al [22,37,38].

During episodes of glycaemic variations even when on treatment, some diabetic patients complain of disturbance of vision such as difficulty in reading and blurred vision (with their own glasses for those with spectacle correction and without glasses for those without spectacle correction or refractive error) because of refractive changes. [1] If a new prescription for spectacles is made at that time, there is a possibility that the new spectacles will soon become inadequate. This phenomenon causes transient refractive changes due to acute changes in plasma glucose levels. Because poor glycaemic control is significantly associated with myopia among DM patients and since there is no general agreement about the influence of diabetes mellitus on refraction, subjects who had poor glycaemic control by FBS/HBA1C results **(table VIII)** were not excluded from the analysis of refractive errors in this study. [16,23,26,27]

Moreover, the available data are conflicting. Many other authors, who investigated the effect of acute changes in plasma glucose levels, have reported that decreasing plasma glucose levels causes hyperopic change. [13,28] It was also reported that a hyperopic change occurred regardless of whether the plasma glucose level increased or decreased. [17] Some investigators have observed both myopic and hyperopic changes in diabetic eyes. [18] Thus, the underlying mechanism of the relationship between plasma glucose concentration and refractive change in diabetics remains to be established. Several papers have reported that an abrupt reduction in plasma glucose in diabetic patients with marked hyperglycaemia induced transient hyperopia. [13,26,27,28]

Refractive changes associated with diabetes mellitus which are due to changes in blood sugar levels, are both acute and chronic. Regarding chronic refractive changes in diabetic patients, Duke-Elder reported that hyperglycaemia led to the development of myopia, while hypoglycaemia led to the development of hyperopia. [26] Analysis of the pattern of refractive errors among patients with poor control of HBA1C/FBS at first presentation, still showed that many patients were myopic (26.1% among patients with HBA1C > 7.3% and 38.9% among patients with FBS > 10.1 mmol/l) **(figure XIV)**. Further analysis of the pattern of refractive errors among patients with good control of HBA1C/FBS at presentation, still showed that many patients were myopic (52.0% for patients with HBA1C $\leq$ 7.3% and 40.0% for patients with FBS $\leq$ 10.1 mmol/l **(figure XIII)**. Therefore, the high prevalence of myopia in this study may be due to chronic refractive changes The overall prevalence of myopia (39.5%) in this group of African type II DM patients is not much higher than in white DM patients, as was shown in the study by Fledelius et al.

The diabetics (representing 762 eyes) in the study by Fledelius et al, showed a shift towards negative refractive values (37.9% with myopia) as compared to non-diabetics (27.5%). The diabetic surplus was due to low degree myopia cases and the association between myopia and (well-controlled) diabetes seemed to be a new observation. [20]

Some of the patients had high values of HBA1C and FBS and in some cases both HBA1C and FBS were high within the same patient (correlation coefficient between HBA1C and FBS (rho=0.188, p-value=0.045, n = 96, at first presentation). In this study, it was difficulty to control for metabolic influences on refractive status. To estimate the short term fluctuation in refraction caused by current level of metabolic control, the power of patients' own distance glasses for 31(32.3%) patients and the measured refraction at first presentation were correlated, statistically significant correlations were found (rho=0.945, p=0.001) **(table VI)**. There was no statistical significance between the correlation of baseline refractive power and indicators of glycaemic control for these 31(32.3%) patients. Therefore, our analysis of the relations between power of glasses and actual measured refractive power and indicators of glycaemic control at first presentation suggest that the results of our study may not have been influenced by acute dysregulation of diabetes mellitus. This point was further strengthened when the refractive errors were found to be relatively stable 2 weeks later when 87.5% of the patients were reexamined. There was a statistically significant correlation between refractive status at first presentation and day 14 (rho=0.977, p=0.001). This strongly suggested that our prevalence calculations for refractive errors in this study were unlikely to be of acute metabolic dysregulation.

Previous studies investigating the relationship between refractive status and indicators of glycaemic control have enrolled very few patients with poor glycaemic control and have correlated changes in refraction to FBS or HBA1C. In the studies done by Fumiki et al and Giusti et al, patients with acute metabolic dysregulation were followed up in order to establish the correlations of fluctuations in FBS/HBA1C with refractive changes. [26,27] In the present study, 52.1% of the patients were fairly well controlled (as per HBA1C and FBS) (**figures X & XI).** We did not follow up patients regularly except for 87.5% who had a repeat examination 2 weeks later. Therefore, it was not possible to establish the correlation of fluctuations in FBS/HBA1C with refractive changes as our patients showed stable refractive status 2 weeks later (rho=0.977, p=0.001 correlations for refractive status at first and second presentation). The correlations done in this study between baseline refractive status and FBS/HBA1C at first presentation did not reach statistical significance except for hypermetropia versus HBA1C (**figure XVIb,** Rho=0.401, p-value=0.014). Though there was no statistically significant correlation between baseline refractive status with HBA1C or FBS **(figures XVa & b and XVIa)**, it is still necessary to request for FBS or HBA1C results before issuing a spectacle prescription to diabetics. What may be more important to consider when writing an optical prescription is a stable refractive status on consecutive examinations as was found in 87.5% of the patients who had a repeat examination on the 14$^{th}$ day of the study. The scatter graphs for baseline refractive status and HBA1C/FBS done at first presentation in 96 patients all showed a similar trend of a myopic shift as the blood sugar increased or decreased as shown in **(figures XVa &b and XVIa & b)**. The scatter graphs for refractive status and FBS obtained on the 14$^{th}$ of the study for each of the 84 (87.5%) patients showed a similar trend, indicating that our

patients may have had stable refractive errors. The graphs in **appendix C** show correlations between refractive status and indicators of glycaemic control of the 84 (87.5%) patients at second presentation.

## 12.0 CONCLUSIONS:

- The study patients had poor glycaemic control i.e. 47.9% had HBA1C > 7.3% while 47.9% had FBS > 10.1 mmol/l.
- Refractive errors were seen in 58.5% of the patients, myopia was the commonest refractive error (39.5%) while 18.9% were hypermetropic.
- There was no statistically significant relationship between baseline refractive status and indicators of glycaemic control except for hypermetropic refractive status and HBA1C (rho=0.401, p-value=0.014).
- There was no significant relationship between refractive status and DR.
- The number of DM patients having eye examination for the first time was less than in previous studies.

## 13.0 LIMITATIONS:

The main limitations of the study were:

- Financial constraints which could not enable us do more investigations for glycaemic control; hence not more than 96 patients could be enrolled.
- No patients with advanced DR were seen.

## 14.0 RECOMMENDATIONS:

- A study looking at the relationship between refractive status and DR should be conducted on patients with DR.
- According to the results of this study, it is not mandatory to ask for HBA1C or FBS results before issuing spectacle prescription to adult patients with type II diabetes mellitus. However, there is need to emphasize the need for good glycaemic control to minimize the other ocular complications. A similar study should be done on young people with type I diabetes mellitus.

## APPENDIX A:

### DY PROJECT EXAMINATION SHEET

**nographic data and previous medical history (including ophthalmic)**

e _____ IP/OP # _____ Study # _____

me _____ Sex/Age _____

ration of diabetes in years: _____

ode of treatment: _____ Diet / OHA / Insulin

st ocular surgery: ____ cataract / laser/ glaucoma surgery / others _____

ast medical / surgical history: renal / cardiac / diabetic foot / hypertension / others

ttendance of DM eye clinic: Regular patient / Lost to follow up / New patient

Wearing spectacles at first presentation: ___ Yes / No

Power of spectacles: RE _____ LE _____

**Presenting visual symptoms:**

None / transient visual changes / poor far vision / poor near vision / poor far and near vision

**Eye examination findings:**

Visual acuity without correction: RE _____ LE _____

Visual acuity with correction (best): RE _____ LE _____

Retinoscopy: RE _____ LE _____

Prescription: RE _____ LE _____

**Clinical findings:**

| | RE | LE |
|---|---|---|
| EOM | | |
| LIDS | | |
| IOP | | |
| CONJUCTIVA | | |
| CORNEA | | |
| AC | | |
| IRIS | | |
| LENS | | |
| VITREOUS | | |
| OPTIC DISC | | |

**Grading of diabetic retinopathy:**

| | RE | LE |
|---|---|---|
| Normal/Minimal NPDR | | |
| MILD NPDR: | | |
| Dot/Blot heamorrhages | | |
| Micro aneurisms | | |
| Hard exudates | | |
| Macular edema | | |
| MODERATE NPDR: | | |
| Cotton wool spots | | |
| Venous beading/Loops | | |

SEVERE NPDR:

4 quadrant intraretinal heamorrhages_____

2 quadrant venous beading_____

1 quadrant intraretinal microvascular abnormalities _____

PROLIFERATIVE DR

New vessels at the disc_____

New vessels elsewhere_____

Fibrovascular tissue_____

Traction retinal detachment_____

Vitreous heamorrhage_____

Grade of retinopathy: _____

Laser marks _____ central/peripheral

Indication for laser: _____

**Laboratory instigations**

FBS (mmol/l) _____ HBA1C (%) _____

Repeat FBS mmol/l (on day 14)_____

# 16.0 APPENDIX B

## CONSENT EXPLANATION

I am Dr Mwale and would like to give you information on a study on the relationship between diabetes mellitus and the eye, which I am conducting.

**Diabetes Mellitus**

Diabetes is a systemic disease characterized by sustained high levels of sugar in the blood due to a lack of or reduced efficacy of insulin produced by the body. As a result the cells of the body don't get enough sugar, which is their main source of energy.

Complications of diabetes include coma, disorders of the heart and blood vessels as well as eye problems. Examples of eye problems include infections, cataracts, double vision and transient poor vision and retinopathy.

Diabetic retinopathy is better delayed, as it is a blinding disease, which sets in early, in patients with poorly controlled blood sugar and affects both eyes. Other than having diabetes reviews, diabetics require regular eye checks so that the progression of the disease can be monitored and necessary interventions like laser or vitrectomy can be under taken at the right time.

The refractive status in diabetics has been shown to be different from the general population and the degree of the refractive error (myopia) has been shown to be protective against retinopathy.

**Investigations**

In this study it will be important to check your FBS (short term) and HBA1C (long term control) so that I can relate the status of your eye to the diabetes after eye examination.

**Eye Examination**

The eye examination will include refraction and looking at the eye with a machine which has a magnifier to check for retinopathy after dilating the eye with drops to get a wide view inside the eye.

Patients with interesting fundus findings will have fundus photos done and no one would be able to identify a person from such pictures. Such photos will be used only for the purpose of the study and will remain the property of UON, at KNH. You will be given copies of the photos on demand.

**Confidentiality**

All personal information gathered from you as my patient in this study, will be kept confidential and will be used for the purpose of demonstrating the objectives of the study.

**Informed Consent**

For you to participate in this study, a signed informed consent is required from you. The eye check is free and necessary interventions will be communicated to you. The two blood investigations will be paid for through the study expenses.

**CONSENT FORM**

I ..... of .....

agree to take part in this study of full ocular examination on this day .....

Dr Mwale of UON has fully explained to me the nature of the study and that it is non invasive and therefore pose no risk to me.

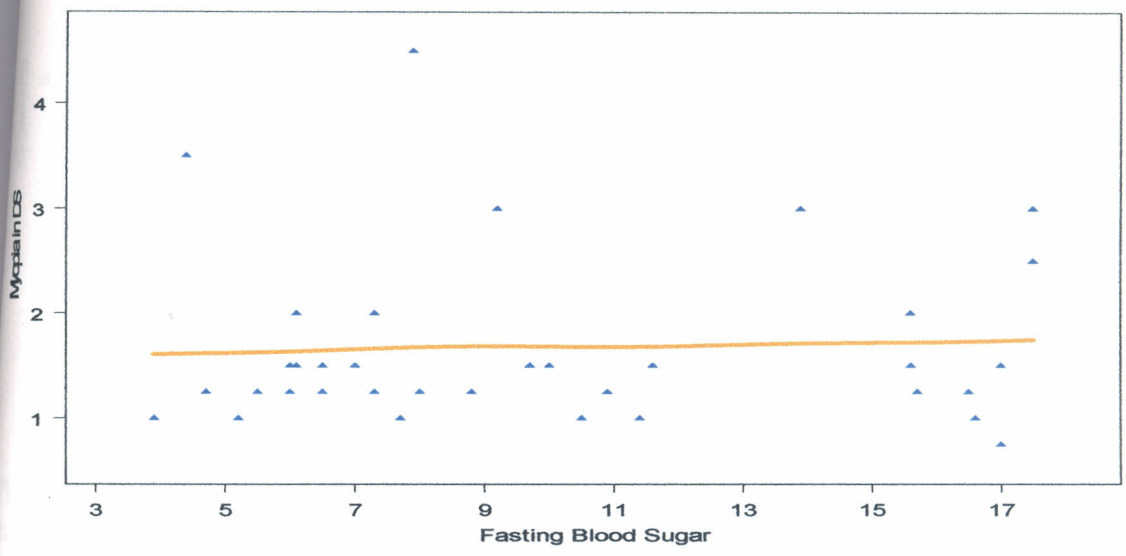
Sign/Thumb print (patient) .....

Sign (Dr. Mwale) ..... Date .....

Sign (Witness) .....Date .....

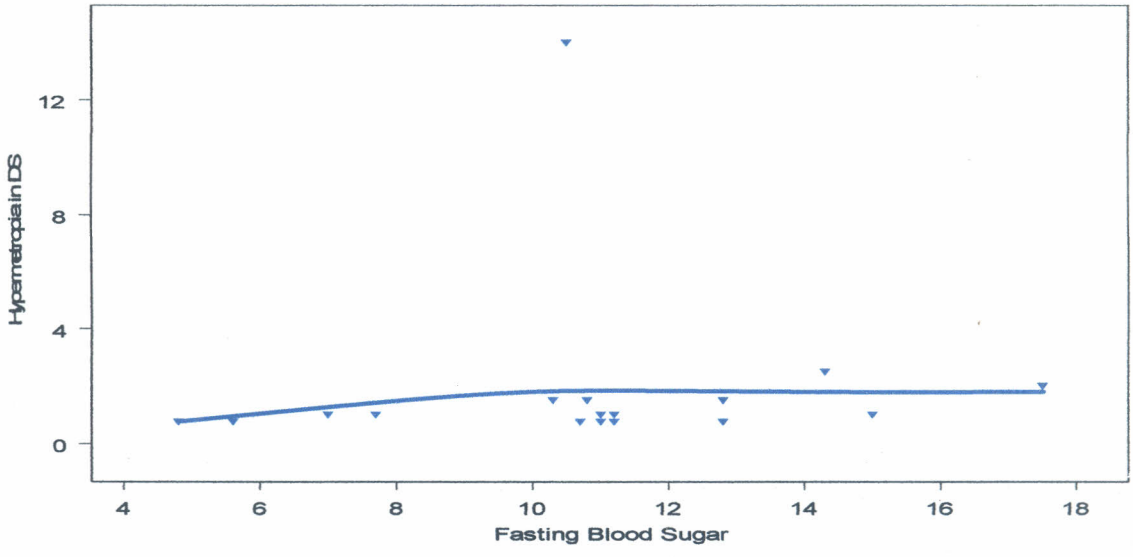
## 7.0 APPENDIX C:

**gure XVIIa: Relationship between myopia and FBS in mmol/l on day 14 of the udy (N=57 eyes):**



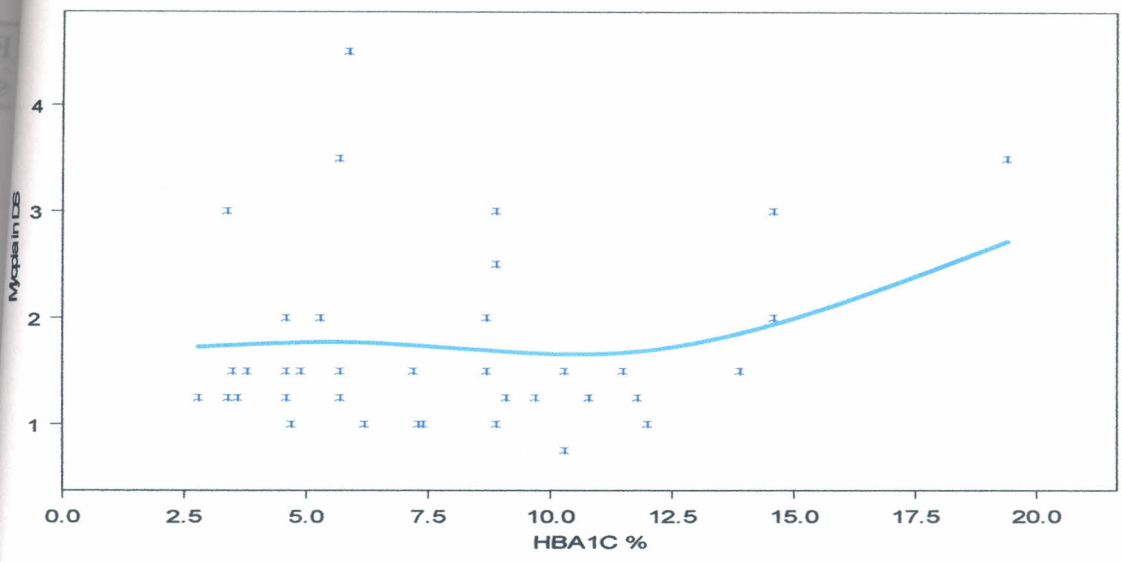

There was no correlation between myopia and FBS (Rho = 0.135, P-value = 0.316).

**Figure XVIIb: Relationship between hypermetropia and FBS in mmol/l on day 14 of the study (N=28 eyes):**



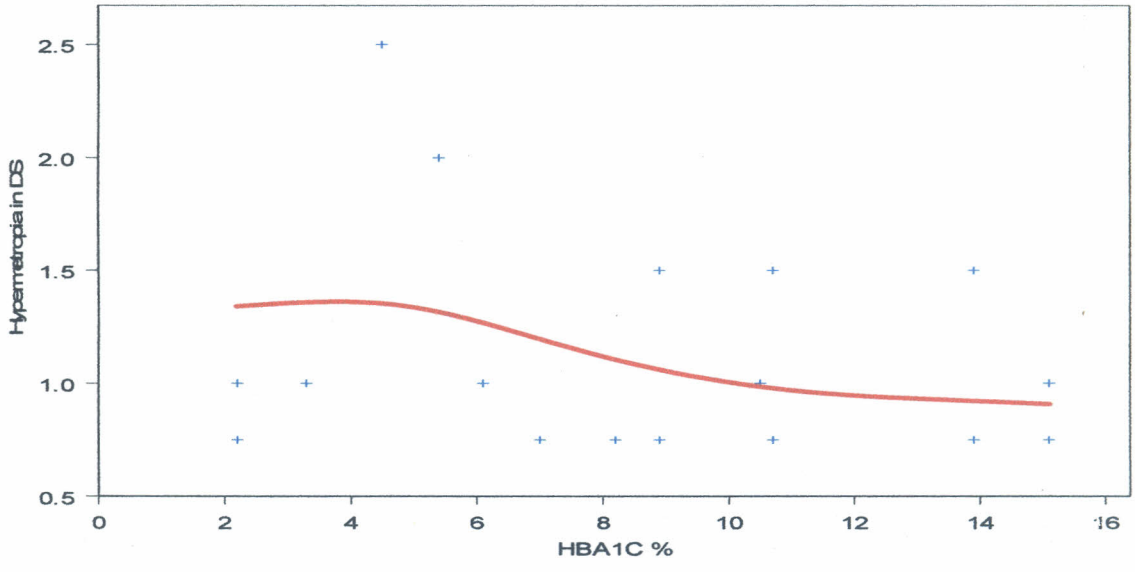

There was no statistically significant correlation between hypermetropia and FBS (rho = 0.116, p-value = 0.558). There was a slight myopic shift as the FBS result decreased below 12.5%.

**gure XVIIIa: Relationship between myopia and HBA1C% on day 14 (N=57 eyes):**




There was a slight myopic shift as the HBA1C result increased beyond 10%. Overall, there was no statistically significant correlation between myopia and HBA1C results (rho = 0.257, p-value = 0.054).

**Figure XVIIIb: Relationship between hypermetropia and HBA1C% on day 14 (N=28 eyes):**




There was a statistically significant correlation between hypermetropia and HBA1C results (Rho = 0.443, p – value = 0.018).

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